IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Title: Inert Tactical Weapons System and Method of Use	)	
Inventor: Ham, J	)	On Appeal
Serial No.: 10/738417	)	
Filing Date: Dec. 17, 2003	)	

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-`1450

Response to Notification of Non-Compliant Appeal Brief

Enclosed please find a copy of the cited art and the legal citations noted in the appeal brief which was filed in September, 2006. The art of record and the legal cites were filed with the brief but the mail room evidently lost the attachments. A copy of the Notification is filed herewith and it is noted that it took months for the Office to issue this Notification.

A review of the Appeal brief itself notes that there is not problem with it. The art of record was entered into the case with the second rejection The two documents groups are listed as appendices hereto. It is assumed that the Examiner can ascertain what reference is what in his reply brief or does the office now require spoon-feeding of

Examiners? The discussion of the references appears on pages 3 through 7 of the brief.

The appendices are noted as Appendix IX for the prior art relied upon by the Examiner and Appendix X is the list of legal citations in the Appeal Brief.

Also attached is a Request for a two month Extension of Time with an accompanying check for a small entity.

Should there by any other issue before the Office it is requested to call the undersigned attorney of record so more time will not be wasted in the prosecution of this application.

Respectfully submitted,

James W. Hiney
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Certification of Mailing

I, James W. Hiney, do hereby certify that an executed copy of this response was deposted, Express Mail Postage No. EB 314291765 US, prepaid, this 12th day of October, 2007 addressed to Commissioner for Patents, Board of Appeals, P. O. Box 1450, Alexandria, VA 22313-1450.

James W. Hiney

Notification of Non-Compliant Appeal Brief (37 CFR 41.37)	Application No.	Applicant(s)	
	10/738,417	HAM, JERRY D.	
	Examiner	Art Unit	
	Stephen Johnson	3641	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

The Appeal Brief filed on *19 January 2007* is defective for failure to comply with one or more provisions of 37 CFR 41.37.

To avoid dismissal of the appeal, applicant must file anamended brief or other appropriate correction (see MPEP 1205.03) within **ONE MONTH or THIRTY DAYS** from the mailing date of this Notification, whichever is longer. **EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136.**

1. ☒ The brief does not contain the items required under 37 CFR 41.37(c), or the items are not under the proper heading or in the proper order.

2. ☐ The brief does not contain a statement of the status of all claims, (e.g., rejected, allowed, withdrawn, objected to, canceled), or does not identify the appealed claims (37 CFR 41.37(c)(1)(iii)).

3. ☐ At least one amendment has been filed subsequent to the final rejection, and the brief does not contain a statement of the status of each such amendment (37 CFR 41.37(c)(1)(iv)).

4. ☐ (a) The brief does not contain a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, referring to the specification by page and line number and to the drawings, if any, by reference characters; and/or (b) the brief fails to: (1) identify, for each independent claim involved in the appeal and for each dependent claim argued separately, every means plus function and step plus function under 35 U.S.C. 112, sixth paragraph, and/or (2) set forth the structure, material, or acts described in the specification as corresponding to each claimed function with reference to the specification by page and line number, and to the drawings, if any, by reference characters (37 CFR 41.37(c)(1)(v)).

5. ☐ The brief does not contain a concise statement of each ground of rejection presented for review (37 CFR 41.37(c)(1)(vi))

6. ☐ The brief does not present an argument under a separate heading for each ground of rejection on appeal (37 CFR 41.37(c)(1)(vii)).

7. ☐ The brief does not contain a correct copy of the appealed claims as an appendix thereto (37 CFR 41.37(c)(1)(viii)).

8. ☒ The brief does not contain copies of the evidence submitted under 37 CFR 1.130, 1.131, or 1.132 or of any other evidence entered by the examiner **and relied upon by appellant in the appeal**, along with a statement setting forth where in the record that evidence was entered by the examiner, as an appendix thereto (37 CFR 41.37(c)(1)(ix)).

9. ☒ The brief does not contain copies of the decisions rendered by a court or the Board in the proceeding identified in the Related Appeals and Interferences section of the brief as an appendix thereto (37 CFR 41.37(c)(1)(x)).

10. ☐ Other (including any explanation in support of the above items):

8. and 9. Evidence Appendix and Related Proceedings Appendix: These two sections are missiing from this appeal brief. If nothing is being submitted with these sections, an indication of "NONE" is required.

Leneetha L. Dyar
Patent Appeal Center Specialist

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/738,417	12/[illegible]/2003	Jerry D. Ham		8341

7590 07/30/2007

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EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED: 07/30/2007

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Notification of Non-Compliant Appeal Brief	10/738,417	HAM, JERRY D.

Appendix IX

Serial No. 10/738417 Tactical Weapon System and Method of Use

Listing of Patents

No.	Inventor	date
2,813, 753	Roberts	Nov. 19, 1957
2,857,005	Medlock	Oct. 21, 1958
5,062,486	McClenahan	Nov. 5, 1991
5,651,417	Coughlin	Jul. 29, 1997

Appendix X

Serial No. 10/738417 Tactical Weapon System and Method of Use

Listing of Legal Citations

In Re Roland N. Francalossi and Mark T. Wajer, 681 F. 2d 792, 1982 CCPA, Lexis 126 215 USPQ (BNA) 569

Hybritech Incorporated, Appellant v. Monoclonal Antibodies, Inc. Appellee 802 F. 2d 1367, 1986 U. S. App Lexis 20347, 231 USPQ (BNA) 81

ACS Hospital Systems, Inc.v. Montefiore Hospital and Wells National Services Corporation 732 F2d 1572, 1984 U. S. App Lexis 15027, 221 USPQ (BNA) 929

In Re Vamco Machine and Tool Co, Inc. 752 F 2d. 1564, 1985 U. S. App. Lexis 14691, 224 USPQ (BNA) 617

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*752 F.2d 1564, *; 1985 U.S. App. LEXIS 14691, **; 224 U.S.P.Q. (BNA) 617*

IN RE VAMCO MACHINE AND TOOL, INC.

No. 84-1383

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

752 F.2d 1564; 1985 U.S. App. LEXIS 14691; 224 U.S.P.Q. (BNA) 617

January 17, 1985

PRIOR HISTORY: [**1]

Appealed from: U.S. Patent and Trademark Office Board of Appeals.

CASE SUMMARY

PROCEDURAL POSTURE: Appellant, the assignee of a patent on a machine, sought review of the judgment of the United States Patent and Trademark Office Board of Appeals, which affirmed appellee examiner's rejection of the assignee's reissue patent claims, which had been extensively amended, upon a finding of obviousness from prior art pursuant to 35 U.S.C.S. § 103.

OVERVIEW: The assignee obtained rights to a patent on a machine issued in 1969 with three claims. After the discovery of some new prior art, the assignee applied for reissue of the patent with extensively amended claims, and the patent was reissued in 1979. The assignee thereafter brought suit on the reissue patent for infringement by another. A reexamination of the reissued patent took place, and the examiner rejected the patent on the ground of obviousness from the prior art pursuant to 35 U.S.C.S. § 103. After the board of appeals upheld that decision, the assignee appealed to the court. The court affirmed the decision. The court found that the finding of obviousness was

fully justified because one of ordinary skill in machine design would have had no difficulty in designing the prior art apparatus into the assignee's reissued patent machine. The court further found that no nexus had been established between the commercial success of the assignee's machine and the subject matter claimed in the original 1969 patent.

OUTCOME: The court upheld the board of appeals' decision, affirming the rejection of the reissued patent claims.

CORE TERMS: patent, feed, drive, gear, sprocket, feed roll, invention, feeder, idler, stock, shaft, roll, examiner, chain, reissue, compound, cam, disclosure, power driven, reexamination, driven, output, crankshaft, varied, specification, obviousness, original patent, blind spots, disclose, geared

LexisNexis(R) Headnotes ◆ Hide Headnotes

Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > General Overview
Patent Law > Nonobviousness > Elements & Tests > Prior Art
Patent Law > U.S. Patent & Trademark Office Proceedings > Reexaminations

HN1 A district court's appellate jurisdiction in a reexamination proceeding is provided by 35 U.S.C.S. § 306, 35 U.S.C.S. § 141, and 28 U.S.C.S. § 1295(a)(4)(A).

Patent Law > Nonobviousness > Elements & Tests > General Overview

HN2 Evidence rising out of the so-called "secondary considerations" must always when present be considered en route to a determination of obviousness.

Patent Law > Claims & Specifications > Definiteness > General Overview
Patent Law > Claims & Specifications > Enablement Requirement > General Overview

HN3 Claims in patents are required by 35 U.S.C.S. § 112. The function of claims is (a) to point out what the invention is in such a way as to distinguish it from what was previously known, i.e., from the prior art; and (b) to define the scope of protection afforded by the patent.

COUNSEL: Arland T. Stein, Reed, Smith, Shaw and McClay, of Pittsburgh, Pennsylvania, argued for Appellant. With him on the brief were Frederick H. Colen and Tracey G. Benson.

Henry W. Tarring, II, Associate Solicitor, of Arlington, Virginia, argued for Appellee. With him on the brief were Joseph F. Nakamura, Solicitor and Jere W. Sears, Deputy Solicitor.

JUDGES: Rich, Circuit Judge, Nichols, Senior Circuit Judge, and Newman, Circuit Judge.

OPINION BY: RICH

OPINION: [*1565] RICH, Circuit Judge.

This appeal is from the U.S. Patent and Trademark Office (PTO) Board of Appeals (board) decision of April 12, 1984, affirming the examiner's rejection, in a reexamination proceeding, of all claims of patent No. Re. 29,795 issued to Vamco Machine and Tool, Inc. (Vamco), assignee of the inventor, Harry Eyberger. The patent title is "Self-Contained Feed Roll for Power Punch Presses." We affirm.

How This Case Got Here

The original Eyberger patent, No. 3,483,782, issued December 16, 1969, with three claims. After the discovery of some new prior art (apparently the V & O feeder

hereinafter discussed), Vamco applied for reissue [**2] of the patent with extensively amended claims on Dec. 16, 1977, and the patent was reissued on Oct. 10, 1978, with claims 1-9. The original and reissue file histories are not before us. Vamco brought suit on the reissue patent for infringement by F. J. Littell Machine Company in the District Court for the Northern District of Illinois, Eastern Division. We copy the following paragraphs from Vamco's statement in the PTO under 37 CFR § 1.510(b) in the reexamination petition:

> On January 28, 1982 Judge Bua issued an order (Exhibit 1) in which the Defendant Littell was ordered to make a diligent search for all prior art and file the same with the Court.
>
> Plaintiff, Vamco, was ordered within 90 days of January 28, 1982 to request reexamination of United States Patent Re 29,795. Plaintiff was also ordered to advise the United States Patent Office of all the prior art filed in Judge Bua's Court and served on Plaintiff, Vamco, by Defendant, Littell. The Defendant on February 25, 1982 submitted a Prior Art Statement Pursuant To The Order of January 27, 1982 (Exhibit 2).

Judge Bua's order, Exhibit 1, which states that it is "for the purpose of avoiding piecemeal proceedings [**3] and litigation, for the purpose of conserving judicial resources, and for the purpose of utilizing the recently enacted laws of the United States" (obviously referring to reexamination proceedings under 35 USC Chapter 30, which added §§ 301-307 on December 12, 1980), also granted plaintiff's motion for voluntary [*1566] dismissal without prejudice and granted plaintiff leave to file a motion to vacate the order within thirty days after the PTO completed reexamination, saying:

> 6. Upon Plaintiff's filing of the motion to vacate . . . this matter will be reinstated before this court, this matter will retain its original docket number and this matter will proceed on the complaint originally filed by Plaintiff in this action.

Pursuant to the order, defendant Littell filed its prior art statement February 25, 1982, listing nineteen U.S. prior art patents, and Vamco obediently told the PTO about them while arguing no substantial new issue of patentability was raised.

The request for reexamination was granted on June 8, 1982, the PTO finding that a substantial new question of patentability was raised, and took its course through several examiner's letters and responses [**4] and the filing of several affidavits until a final rejection resulted on December 16, 1982. Following that, there was a personal interview with the examiner attended by Vamco's attorney and Mr. J.P. Gentile, who is an affiant and an officer of Vamco (a family-owned company), and Edward S. Paris, another affiant employed by Vamco. Five more affidavits were thereafter filed, appeal to the board was taken, and the examiner filed his Answer. Vamco's attorney then realized he could overcome one of the examiner's principal points by a clarifying amendment to the claims, got the examiner to agree to it in a telephone interview, and the examiner wrapped it up with a Supplemental Answer. Claims 1-9, all the claims in the patent, were on appeal to the board, which affirmed, and the same are on appeal to us. The references relied on had by then been reduced to four, in support of the sole ground of rejection which is obviousness from the prior art, 35 USC § 103. The references are:

"V & O Heavy Duty Roller Gear Feeds," a catalog of V & O Press Company, Inc. (hereinafter V & O)			
Sweet	U.S. patent	363,776	May 24, 1887
La Ganke et al.	(La Ganke)	1,408,894	Mar. 7, 1922
Wittek		1,796,417	Mar. 17, 1931

[**5]

Our HN1 appellate jurisdiction in this reexamination proceeding is provided by 35 USC § 306, 35 USC § 141, and 28 USC § 1295(a)(4)(A).

Issue

The sole issue before us is whether the board erred in holding the invention, as defined in claims 1-9, construed in the light of the disclosure in the specification of Reissue patent No. 29,795, would have been obvious within the meaning of § 103 from the disclosures of the prior art references relied on to reject them. A subissue is whether commercial success and other "secondary considerations" were established for Eyberger's invention.

The Invention Disclosed in the Patent

No issue has been raised with respect to what is disclosed, but the precise nature of the disclosure is of considerable significance, especially with relation to appellant Vamco's heavy reliance on the so-called "secondary considerations" which must be considered in passing on obviousness vel non. We therefore point out certain aspects of the disclosure which we deem significant. We note in passing that Harry Eyberger, the named inventor; on the record before us, is a mere name. Nothing is disclosed about him or about the making of his invention. The [**6] dramatis personae in this case are officers and employees of Vamco, an outside consulting engineer, a professor, and a customer who have submitted affidavits on Vamco's behalf.

The invention relates to an accessory for power punch presses which stamp out metal parts, large and small, from sheet metal which has to be fed between the stamping or punching dies and is often fed from rolls. At the top of such a press is a continuously rotating shaft which can be used as a source of power to run a strip-feeding mechanism. What Eyberger's patent says he invented is, in broad terms as set forth in the "Abstract":

> A self-contained unit to be attached to a power punch press to provide a feed for stock being fed to the press. The unit contains a direct drive from the punch press crankshaft to feed rolls which are [*1567] located adjacent to the table of the press. A non-slip, positive, drive is provided. . . .

In stating what had been wrong with prior feeders, he said many of them "contained clutches and brakes, which did not permit positive drive . . . clutches wore or brakes failed causing spoilage of pieces and damage to tooling." His invention, he said, "provides [**7] positive, direct drive between the crankshaft of the punch press and the feed rolls. There is no slippage, clutches, brakes, or other friction-type mechanism which can cause loss of timing or costly repairs." Another aspect was a "novel release means which permits the feed stock . . . to be released from the feed rolls during the pressing . . . ." Notably missing from his list of stated "objects" of his invention is any mention of providing a more accurate or more precise or speedier setting or adjustment of the amount by which the stock is fed to the press, which has become the central theme of Vamco's arguments for patentability, the significance of which will appear later.

Below is Fig. 1 of the patent, which is "a front elevational view of the feed roll unit of the present invention with a portion of the housing removed and showing a portion of the punch press in phantom view."

[*1568] [SEE FIG. 1 IN ORIGINAL]
The side of the phantom press is at 12, its crankshaft is 14, driving the feed unit through belts 20 and 24. The power-driven feed roll is 40 and 50 is the releasable idler feed roll. Attention is directed to the roller chains 34 and 42 which connect sprockets [**8] (after the manner of bicycle drives) 28, 30, and 38 which will be better understood from Fig. 3 below, which is a "diagrammatic perspective representation of the working portions of the feed roll mechanism . . . in semi-schematic form." (We have added "S" to the stock, "30a" and "30b" to the compound sprocket and also the brackets with references to elements named in claim 1. In the schematic, the sprocket teeth have been omitted.)

[*1569] [SEE FIG. 3 IN ORIGINAL]

We can now describe the parts of the feeder unit and their relationship and operation. At the top, is the crankshaft 14 of the punch press equipped with a pulley 16, which drives, through cleated belts 20 and 24 and pulley 18, pulley 22 on an "index drive 26." This is a commercially available right-angle drive which changes the continuous rotary motion of shaft 26a into step-by-step incremental rotary motion in shaft 26b so as to feed the stock to the press intermittently. Output sprocket 28 drives unit 30 which consists of the two sprockets 30a and 30b connected together, through drive chain 34 connected to 30a. Sprocket 30b is connected by chain 42 to feed roll 40's drive sprocket 38. Stock S being fed is [**9] pressed against roll 40 by idler roll 50 but can be released during stamping by electro-pneumatic controls 52, 58, 66, and 60 which

need not be explained, though Eyberger seemed to regard them as an important part of what he invented and claimed in claim 3. The upper die or punch of the press is 12.

With respect to the arguments in this case, the significant disclosure is the double sprocket 30 shown in Figs. 1 and 3 and what the specification of the patent says about it and its closely associated parts. The first statement reads:

> The slotted hole 32a [see Fig. 1 at the bottom] permits adjustment of the idler pully [sic; sprocket] in various positions to accommodate various size chains and pullies to thereby adjust the feed stroke [*1570] of the feed roll unit in a manner to be more fully hereinafter explained.

The latter explanation is under the heading "OPERATION" and is:

> It may be seen that by placing various combinations of sprockets 28, 30 and 38, of different sizes, the amount of lineal motion imparted to the feed stock through power driven feed roll 40 may be varied for any single rotation of crankshaft 14. Thus, the exact length of [**10] feed desired may be controlled by changing the size of the sprockets. The indexing increment can also be increased or decreased by the use of various gear trains (not shown) in place of chains 34 and 42 and sprockets 28, 30 and 38.
>
> When the size of idler sprocket 30 is changed it is positioned along the slotted hole 32a of the support 32 so that drive chain 42 is in proper tension. The chain tensioner sprocket 36 [Fig. 1] is then adjusted to properly tension drive chain 34 so that a direct drive is provided between the index drive 26 and the power driven feed roll 40.

The foregoing is the totality of what the patent has to say on the subject of adjusting the feed and it will be noted that such adjustment involves removing chains from sprockets, removing sprockets from shafts, replacing them with others, and reinstalling and tensioning the chains. It will be further observed that though passing mention is made of the possibility of using "various gear trains," none is shown and none is described, yet, as will appear, this case is argued primarily on the basis of apparatus using gear trains, particularly with respect to "secondary considerations."

In concluding the [**11] specification and summing up what the invention achieves, all the inventor chose to emphasize was that he had provided "a self-contained feed roll unit" which could be "readily installed," which had a "positive drive" and in which "the force on the feed rolls may be released periodically during the pressing operation."

The Invention Claimed

Of the nine claims, only claim 1 is independent. Although the PTO rejections of various claims rely on various combinations of prior art references, it will suffice to discuss claim 1 in its final, reissued, and subsequently amended form. It reads:

> A self-contained feed roll unit for a power punch press having a crankshaft rotating in timed relation to the pressing portion of the operating cycle of said punch press, said feed roll unit comprising:
>
> (a) a power driven feed roll;
> (b) an idler feed roll rotatably supported on a movable frame and normally urged toward said power driven feed roll, said idler feed roll being periodically moved away from said power driven feed roll by feed roll release means to free stock being fed to said power press during the pressing portion of said power press operating cycle;

(c) an index [**12] drive having an input shaft to receive continuous, uniform rotary motion and an output shaft transmitting non-continuous, incremental rotary motion;
(d) first positive drive means drivingly connecting said index drive input shaft to said power press crankshaft; and
(e) second positive drive means including a first drive member connected to said index drive output shaft, a driven member connected to said power driven feed roll, *a compound idler member having different diameters drivingly connected to said first drive member and said driven member to thereby drivingly connect said index drive output shaft to said power driven feed roll*, said second positive drive means being adjustable to vary the ratio of the angular velocity of said index drive output shaft relative to said power driven feed roll. [Emphasis ours.]

The eight dependent claims, by their numbers, add the following additional details or [*1571] limitations, stated for simplicity in our own terms:

2. element (e) in claim 1 is formed of chains and sprockets and the length of stock fed is varied by changing the size of the sprockets.
3. the "feed roll release means" of (b) in claim [**13] 1 comprises certain named compressed air, cam, solenoid valve, and pilot valve apparatus, which the specification describes in detail. (A featured aspect of the invention as described and claimed in the patent.)
4. the length of stock fed is varied by changing at least one (in (e)) of the first drive member, compound idler drive member, or the driven member.
5. the length of stock fed is varied by changing the size of the "compound idler drive member."
6. the stock fed is varied by changing the size of the "first drive member" in (e) of claim 1.
7. the stock fed is varied by changing the size of the "driven member" in (e) of claim 1.
8. the unit of claim 1 contains means permitting the mounting of different drive, idler, and driven members so stock fed can be varied by changing their sizes.
9. the unit contains mounting means for the index drive output shaft in *fixed* spaced relation to the feed roll (i.e., the relation of 28 to 38, Fig. 3).

It is of interest to note that most of the italicized wording of clause (e) in claim 1 and all of dependent claims 4-9 which refer back to it was added by the application to reissue the original patent filed eight [**14] years to the day after the issuance of the original patent. Clause (e) and the language in claims 4, 5, and 8 was further amended at the very end of the reexamination, more than 13 1/2 years after the original patent, to avoid a prior art patent (Hallenbeck) heavily relied on by the examiner, to specify that the "idler member" was "compound," i.e., consisted of two sprockets "having different diameters" connected together. In the reissue patent, it was claimed 84-1383 simply as *an* "idler member." In the original patent it was *not recited in the claims at all*, but only included by implication as an *unnamed* part of the "second positive drive means" defined as "being adjustable." n1

- - - - - - - - - - - - - - Footnotes - - - - - - - - - - - - - -

n1 The practical effect of adding this language to (e) of claim 1 and of adding new claims 4-9, was to make it possible to argue the existence of "an inventive concept" which does not appear *in* the original patent, in either its specification or claims. The question is thus raised whether this was not, in effect, an enlargement of the scope of the claims, masquerading as a narrowing, contrary at least to the spirit of 35 USC § 251, last paragraph, which reads:

No reissued patent shall be granted *enlarging the scope of the claims* of the original patent unless applied for *within two years* from the grant of the original patent. [Emphasis ours.]

However, this question was not raised by the PTO.

---------- End Footnotes- ---------- [**15]

The patent will expire December 16, 1986. We find it significant that the claims have been twice altered over the years to keep up with Vamco's commercial interests. (See discussion, infra, on commercial success, etc., of the "Eyberger invention.")

Rejection of the Claims for Obviousness

This appeal is from the decision of the board; but its decision was simply to affirm the examiner's final rejection, which was that all claims except claim 2 would have been prima facie obvious in view of the V & O Catalog taken with La Ganke and Sweet, and claim 2 for the same reason when Wittek was considered, the references listed at the beginning of this opinion.

Our own review of the references leads us to conclude that the PTO position respecting prima facie obviousness was fully justified. The V & O Catalog discloses in words and pictures a power press roll feed driven from the press crankshaft by a chain drive and roller gear ("indexing") unit that imparts intermittent motion to the feed. We quote further:

> On the output shaft of the roller gear unit and the input shaft of the roll feed [*1572] are a pair of pick off gears that transmit the power to the feed. [**16] These pick off gears provide a fast and low cost method of changing feed lengths. By using a standard diameter lower feed roll, feed increments of.001" can be provided. A time consuming change over of costly lower feed rolls is not necessary. Because of this type of construction, friction clutches, brakes with water cooling devices and reciprocating motions are eliminated.

Among listed "features" is an adjustable, cam-operated idler roll n2 release operated by the press slide. Because appellant pressed the point that the V & O feed has only two gears, whereas its feeder has four, the examiner cited Sweet which discloses "gearing for changing speed," for its increase or decrease, and for application "to any kind of machinery." Sweet is cited for its disclosure of a movable and changeable combination gear interposed between the driving and driven gears in a manner similar to Eyberger's combination sprocket 30a-30b. In Sweet, the support for the shaft for the combination gear is slotted, in a manner similar to Eyberger's slotted support 32a for his idler sprocket shaft. Below are figures from Sweet showing three different gear combinations, the combination idler gears [**17] being G-H, G-H', or G'-H. Gear B on the left is the power gear and gear C on the right is the driven gear. The slotted mounting for shaft F of the combination gear is self-evident.

---------- Footnotes ----------

n2 The idler roll of the feed should not be confused with the idler sprocket which drives the lower driven feed roll.

---------- End Footnotes- ----------

[SEE FIGS. 1, 3, 4 and 5 IN ORIGINAL]

[*1573] Wittek discloses another power punch press stock feed with a pair of feed rolls wherein there is a chain-and-sprocket drive for the lower feed roll powered from the press main shaft. It is cited for the statement:

> Since the sprockets 13 and 29 are removable, they may readily be changed to vary the speed of the die mechanism [which carries the feed rolls] and thus cause a more rapid or slower movement of the stock 33 through the die set.

Compare claim 2, supra.

La Ganke also discloses a roll feed for punch presses wherein the upper or idler feed roll is moveable. He provides mechanism, including cams acting on the idler roll [**18] shaft, to release the pressure on the stock while the pressing is in progress, as recited in clause (b) of claim 1, supra.

V & O and La Ganke taken together disclose punch press feeders having everything shown by Eyberger except the compound idler sprocket defined in clause (e) of claim 1, which is worded broadly enough to cover compound gears. The examiner relied on Sweet to show the compound gear speed adjustment which falls within clause (e). It is clear to us that one of ordinary skill in machine design would have had no difficulty in designing the Sweet gear arrangement into the V & O feeder should greater versatility in speed, or length of stock fed, be desired. With no more than that change necessary to arrive at the invention claimed in the Eyberger reissue patent, a rejection of the claims for obviousness was clearly warranted.

Vamco's "Secondary Considerations" Arguments

Of course, HN2 "evidence rising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness." Stratoflex Inc. v. Aeroquip Corp., 713 F.2d 1530, 1538, 218 U.S.P.Q. (BNA) 871, 879 (CAFC 1983). As we believe was done in the PTO, [**19] we shall fully consider the evidence, giving each piece of evidence its appropriate weight, in answer to Vamco's contention that the board disregarded this evidence.

As indicated earlier, appellant submitted several affidavits for the purpose of showing commercial success, the filling of a long-felt need in the art, copying by competitors, advantages of the invention, and in order to submit opinions of "experts" that "the subject matter described and claimed in the Eyberger patent" would not have been obvious to one of ordinary skill in the art in 1967, at the time the invention was made, which was taken to be the year the application for that patent was filed. Vamco also made of record an article on its feeders from "Metal Stamping." The affidavits and the article were considered in detail by the examiner and in the opinion of the board. They found them unpersuasive but for somewhat different reasons. The examiner said in his Answer on the appeal to the board, inter alia, "it is emphasized that it is clear that these affidavits and article relate to the specific commercial embodiment which is simply not disclosed in Requestor's [the one who requests reexamination] patent." The [**20] examiner had earlier pointed out in his Answer that "the commercial embodiment utilized by Requestor and to which specific embodiment many advantages have [been] urged throughout the [Requestor's] Brief bears little or no resemblance to the drawing of the patent in issue [Re. 29,795]." To shed light on what he was talking about, reproduced below is one picture from the "Metal Stamping" article showing Vamco's gear arrangement, allegedly part of the "second positive drive means" of claim 1, clause (e), used in place of Eyberger's sprocket and chain structure shown in Fig. 1, supra. It looks different and it is different, as the examiner pointed out.

[*1574] [SEE ILLUSTRATION IN ORIGINAL]

The main theme of Vamco's arguments here and in the PTO is in essence that the invention "described and claimed in the Eyberger patent" enables the user of its feeder "to vary the stock feed length from.052 inches to 6.000 inches in increments of.0005 inches" by simply changing the set of gears shown above and that there are no "blind spots" in such adjustment, that is to say, there is no dimension, to within at least.001 inch of feed, which cannot be achieved. It is further said [**21] that this can be done in "a few minutes." The Eyberger patent does not disclose or even hint at any such possibilities or even list such accurate feed length changes among the objects of the invention. It states, at most, only that "the exact length of the feed desired may be controlled by changing the size of the 3 sprockets," but does not say how.

The board opinion also considered the affidavits at length but primarily took the position that *no nexus* had been established between the commercial success of the Vamco feeders and the subject matter claimed by Eyberger.

In substance, we agree with both the examiner and the board but for somewhat different reasons, which we shall express as we review the affidavits.

The Affidavits

Patrick J. Gentile, an officer of Vamco, begins by saying his company produces a geared cam feed that is "covered by the claims of Reissue Patent No. 29,795." That is but a layman's opinion on a legal question, and is no indication that Vamco's commercial feeder is *disclosed* in the patent in such fashion that those skilled in the art would be taught how to make Vamco's commercial feeder. Gentile then repeats and amplifies the statement, [**22] which we made above, about micro feed adjustment

possibilities, which, as we also pointed out, are not taught by the patent. He states in conclusory fashion that the *geared cam feed of Vamco* filled a long felt need in the industry because feed "can be accurately changed in a matter of minutes by merely changing the gear train, " a statement clearly not applicable to Eyberger's sprocket and chain structure which would be more cumbersome to disassemble and reassemble and might also involve substitution of different chains, as the patent clearly states. He then says Vamco's feeders are market leaders and that sales have increased from 6 in 1973 to 300 in 1979 but it is not shown how Eyberger's disclosures had anything to do with that. As developed later, there are in fact several other reasons for the market success.

The *first Paris* affidavit is now irrelevant due to the withdrawal of a rejection since it only discusses the Hallenbeck reference, no longer relied on and not of record. The same is true for the second Paris affidavit which presents calculations to show that Vamco's feeder would have fewer blind spots than either Hallenbeck or the V & O feeder modified by the [**23] Hallenbeck teaching. But even so, Eyberger does not even suggest the existence of blind spots and certainly teaches no way to eliminate them.

Professor Erdlac of the University of Pittsburgh Department of Mechanical Engineering, obviously well qualified in his field, repeats in substance the entire specification of the Eyberger patent, most of which is in the prior art, and critical passages from the claims such as clause (e), and analyzes all the references relied on. He then gives his opinion that "the subject matter described and claimed in the Eyberger patent" would not have been obvious in 1967 over the disclosures of the prior art, [*1575] which opinion is not at all surprising. We respect his opinion, for what it is worth, but the question is one of law which we must decide and involves matters other than those he investigated and reports on. Our problem with his lay opinion on patentability, however, is that we have no idea what he means by "the subject matter described and claimed." Does he mean Eyberger's sprocket and chain feeder or does he include the Vamco gear machine as marketed, which he seems to include within the term "claimed"? We too can read this [**24] patent and understand what it *describes*. What it *claims*, however, in terms of the number of different permutations and combinations of sprockets, or of gears, substituted for sprockets with the omission of chains, especially as appellants and Professor Erdlac construe them, is vastly more than the patent describes or teaches, or even suggests.

Clearly, the most important segment of the Erdlac affidavit is his computations showing what an "extremely fine change" in feed length can be produced by changing the number of teeth on the compound sprockets 30a and 30b and the sprockets 28 and 38. From his calculations, Professor Erdlac concludes that "it should be clear that the system of compound *gears* described and claimed in the Eyberger patent will result in extremely fine increments of advance." (Emphasis ours.) We do not dispute his mathematical demonstrations. However, Eyberger's patent, originally or after reissue, never *described* any such possibility, or any system of gears, and not until eight years after it was issued did it *claim*, in claim 1, clause (e), anything more than a "second positive drive means" which was *adjustable* to vary feed roll speed. [**25] n3 Professor Erdlac has taught us in his affidavit how to get very fine adjustments, but the Eyberger patent does not.

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n3 The way original claim 1(e) actually stated it was: "adjustable to vary the ratio of the angular velocity of said index drive output shaft relative to said power driven feed roll," which is, simply, either speed of the first roll or feed of the stock, depending on the terminology one chooses to use.

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In *Graham v. John Deere Co.*, 383 U.S. 1, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966), speaking of the plow shank there involved, the Supreme Court said at page 25:

> Petitioners' argument basing validity on the free-flex theory raised for the first time on appeal is reminiscent of *Lincoln Engineering Co. v. Stewart-Warner Corp.*, 303 U.S. 545, 82 L. Ed. 1008, 58 S. Ct. 662 (1938), where the Court called such an effort "an afterthought. No such function . . . is hinted at in the specifications of the patent. If this were so vital an element in the functioning of the apparatus it is strange [**26] that all mention of it was omitted." [303 U.S. at 550.]

The *Metal Stamping* article (April 1976) on the Vamco feeders becomes very pertinent at this point. It sheds much light on the secret of obtaining fine adjustments and on

how it is actually done in practice. The board dismissed it as "hearsay", a "trade article which is expected to be laudatory"; but we find it of great interest on just what has made the Vamco feeders such a success. This relates in a way to the board's point about nexus. The writer of the article first reports on the great accuracy of Vamco machines. They are handsomely finished and of great precision and made of the best materials. "The Vamco design, developed by Vamco president Pat Gentile [a former toolmaker] reduces feed length changeover . . . to a matter of five minutes or less. The concept is simplicity itself . . . . [A] gear train consisting of four gears has been developed. To change feed length, you change the gear train and readjust the roll release cam." It is then pointed out that a separate set of gears is required for every feed length, but "costs under $100" and is available immediately from stock. That is to say, [**27] the user of the press decides what feed he wants and orders a set of gears from Vamco. *Once he gets them*, they can be installed in minutes. The story continues:

> [*1576] Just as impressive as the design of the feed itself was the program Vamco used to develop the gear configurations required to provide feed lengths over the full range in increments of.001 inch. Since there are four gears in each set, the possible permutations run into the high millions . . . . The computation of just a few of the possible combinations would have required hundreds of man hours. *Vamco solved this problem by developing a computer program* to do the necessary calculations. The result is a thick set of print-outs in which five gear combinations are established for every feed length. Why five? To allow for availability of gears at all times. [Emphasis ours.]

To achieve the remarkable incremental adjustments in steps of.001 inch with no blind spots, which is alleged to be the great advantage of the invention "described and claimed" in the Eyberger patent, one therefore needs not only the gear machine *developed by Pat Gentile* and the appropriate set of gears, but also [**28] either Vamco's computer program or the computer print-outs and must get "a different set of gears for each feed length," according to the article. n4 The program would be essential to the user who wishes to overcome "blind spots." It is clear that the patent contains no disclosure which enables even a reader skilled in the art to achieve the great advantages now attributed to the Eyberger invention and relied on to show unobviousness, or to account for the commercial success which is asserted to be indicative of unobviousness.

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n4 The PTO was aware of these print-outs as a page from one of them was submitted by the attorney on two occasions and is of record before us.

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Stephen Miketic's affidavit consists of an extensive recitation of his qualifications, apparently as an expert in industrial management and plant design with long experience, and otherwise is either a copy or paraphrase of most of Professor Erdlac's affidavit, minus the professor's computations. He, of course, is of the opinion that the [**29] "subject matter described and claimed in the Eyberger patent would have been unobvious" in 1967 and has the same opinion as Professor Erdlac as to each of the references relied on by the PTO. He does add some color by saying that a quantum leap would have been required to get from the prior art to the feed unit of the Eyberger patent. However, he seems to equate the Eyberger patent unit of 1967 with the Vamco commercial unit of 1983, itself a quantum leap for which there is no justification. We do not find repetitive opinion affidavits of this type to be of much help in solving patentability problems. What we do find helpful is facts of which we would not otherwise be aware.

Terry L. Wisman is Vice President of Engineering of a manufacturer of metal-forming automatic presses. Though not appearing to be qualified as an expert on patents or patent law, he undertakes to tell what Reissue patent No. 29,795 is all about, saying he has read and understands it. He says the "feed roll unit claimed in the Vamco patent" permits accurate changes in feed length "by changing one or more members of the second positive drive means," talking claim language, and significantly reduces "blind [**30] spots." But he does not explain how. He says that in 1976 his company, Minster Machine Co., began buying Vamco geared cam feed roll units "which are the subject of the Claims 1 and 3-9 of U.S. patent Re. 29,795" to equip its presses, rather than making its own, and that the Vamco units reduced the blind spots in feed lengths to 0.001 inch or less, but he does not explain how. And finally for a third time he says feed lengths on Vamco units can be changed in increments of 0.001 inch or less in a matter of minutes by changing one or more members "in the second positive drive means," in claim language again, without saying how any more explicitly. He concludes by saying "Such flexibility and accuracy was not available until the advent of the Vamco feed roll which is described and claimed in U.S. Patent No. Re. 29,795."

[*1577] Wissman's omission of claim 2 from his above enumeration of *claims* was well advised. It is the claim specific to what the Eyberger patent discloses, wherein the "second positive drive means" "is formed of chains and sprockets" and stock feed is varied by changing them. We fail to see, however, what *claims* have to do with what the Eyberger patent [**31] taught the art or with the Minster Company's election to buy Vamco feeders. Certainly it is not buying Eyberger feeders. As the board said, no nexus has been established between them and the success of Vamco's *product*, which is a combination of superbly built gear feeders and computerized replacement gear supply service.

The second Gentile affidavit ends the story. All it says is that the Vamco geared cam feed discussed in the article in *Metal Stamping* "is a geared cam feed that is described and claimed in U.S. Patent No. Re. 29,795." By now it seems superfluous but we will say it anyway, lest someone has not attentively read the foregoing opinion: The article does *not* discuss the cam feeder described in the patent and the patent does not describe a geared cam feed. What it *claims* n5 has nothing to do with the question of what it was that enjoyed commercial success and filled a felt need in the industry or was copied by competitors.

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n5 HN3 Claims in patents are required by 35 USC § 112, second paragraph. The function of claims is (a) to point out what the invention *is* in such a way as to distinguish it from what was previously known, i.e., from the prior art; and (b) to define the *scope of protection* afforded by the patent. In both of those aspects, claims are not technical descriptions of the disclosed inventions but are legal documents like the descriptions of lands by metes and bounds in a deed which *define the area* conveyed but *do not describe the land*. Because of this characteristic of claims, the commercial success of a machine "claimed" may be due entirely to improvements or modifications made by others to the invention *disclosed* in a patent. Such success, we are holding, is not pertinent to the non-obviousness of the invention disclosed. This is, however, not a holding that *advantages* inherent in what *is* specifically disclosed in a patent are not to be considered in determining non-obviousness.

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In summary, for the foregoing reasons we find no "secondary considerations" in this case having a bearing on the legal issue of the obviousness *of the invention* of the Eyberger reissue patent. We therefore *affirm* the decision of the board which affirmed the examiner's final rejection of claims 1-9 of Reissue patent No. 29,795.

AFFIRMED.

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*732 F.2d 1572, *; 1984 U.S. App. LEXIS 15027, **; 221 U.S.P.Q. (BNA) 929*

ACS HOSPITAL SYSTEMS, INC., Appellant/Cross-Appellee, v. MONTEFIORE HOSPITAL and WELLS NATIONAL SERVICES CORPORATION, Appellees/Cross-Appellants

Appeal Nos. 83-1121, 83-1132

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

732 F.2d 1572; 1984 U.S. App. LEXIS 15027; 221 U.S.P.Q. (BNA) 929

April 27, 1984

PRIOR HISTORY: [**1]

Appealed from: U.S. District Court for the Western District of Pennsylvania.

DISPOSITION: Affirmed in Part and Reversed in Part.

CASE SUMMARY

PROCEDURAL POSTURE: Plaintiff patentee appealed a judgment entered by the United States District Court for the Western District of Pennsylvania, which held that its patent for a hospital television rental system was invalid due to obviousness and that it was not infringed by defendant, an alleged infringer.

OVERVIEW: The court reversed a judgment that held that the patentee's patent for a television rental system was invalid as obvious under 35 U.S.C.S. § 103. The district court's assessments of the scope and content of the prior art, the differences between the claimed subject matter and the prior art, and the level of ordinary skill in the art

were clearly erroneous. None of the prior art references disclosed the use of override switches in a television rental system. Therefore, the judgment of invalidity was incorrect as a matter of law. Because the alleged infringer's system lacked the patentee's claimed limitation of override switches, a judgment that the alleged infringer did not infringe the patent, either literally or under the doctrine of equivalents, was not clearly erroneous and was affirmed.

OUTCOME: The court reversed the judgment, which held that the patentee's patent for a television rental system was invalid as obvious, because the judgment was incorrect as a matter of law. The court affirmed that part of the judgment that held that the alleged infringer's product did not infringe the patent either literally or under the doctrine of equivalents.

CORE TERMS: switch, patent, override, television, switching, actuated, invention, subject matter, rental, relay, actuating, normally, invalidity, invalid, obviousness, clearly erroneous, overriding, receiver, locked, skill, actuate, indicator, infringe, switched, infringement, enabling, matter of law, depressing, overridden, literally

LexisNexis(R) Headnotes ◆ Hide Headnotes

Evidence > Procedural Considerations > Burdens of Proof > Allocation
Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview
Patent Law > Infringement Actions > Defenses > Patent Invalidity > Validity Presumption

HN1 The presumption of patent validity under 35 U.S.C.S. § 282 is never annihilated, destroyed, or even weakened, regardless of what facts are of record. Rather, it is a clear statutory procedural device which assigns to the party asserting invalidity the burden of proving invalidity. The burden of persuasion is, and remains always, on the party asserting invalidity.

Patent Law > Inequitable Conduct > General Overview
Patent Law > Infringement Actions > Defenses > Patent Invalidity > Validity Presumption
Patent Law > U.S. Patent & Trademark Office Proceedings > Continuation Applications > General Overview

HN2 A patent shall be presumed valid. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity. 35 U.S.C.S. § 282.

Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview
Patent Law > Nonobviousness > Elements & Tests > Prior Art
Patent Law > Nonobviousness > Elements & Tests > Secondary Considerations

HN3 35 U.S.C.S. § 103 lends itself to several basic factual inquiries. Under 35 U.S.C.S. § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or non-obviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy.

Patent Law > Infringement Actions > Claim Interpretation > Means Plus Function

HN4 Claims are to be read and construed in light of the specification and the prosecution history of the patent. Further, claims should be so construed, if possible, as to sustain their validity.

Patent Law > Claims & Specifications > Enablement Requirement > General Overview
Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview

Patent Law > Nonobviousness > Evidence & Procedure > Fact & Law Issues

HN5 Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under 35 U.S.C.S. § 103, teachings of references can be combined only if there is some suggestion or incentive to do so.

Patent Law > Infringement Actions > Claim Interpretation > General Overview
Patent Law > Infringement Actions > Infringing Acts > General Overview

HN6 Infringement is determined on the basis of the claims, not on the basis of a comparison with the patentee's commercial embodiment of the claimed invention.

Civil Procedure > Appeals > Standards of Review > Clearly Erroneous Review
Patent Law > Jurisdiction & Review > Standards of Review > General Overview

HN7 Findings of fact are to be construed liberally in support of a judgment.

Civil Procedure > Trials > Bench Trials
Civil Procedure > Appeals > Standards of Review > Clearly Erroneous Review

HN8 Where the trial court fails to make findings, the judgment will normally be vacated and the action remanded for appropriate findings to be made. Where a full understanding may be had without the aid of separate findings, however, the courts recognize a narrow exception to that general rule.

Civil Procedure > Trials > Bench Trials
Civil Procedure > Appeals > Standards of Review > Clearly Erroneous Review

HN9 The ultimate finding of fact in a case, whether initially by the trial court, or as affirmed on appeal, rests on the same underpinnings, i.e., the necessary subsidiary facts, supported by evidence of record, that lead to that ultimate finding. Where the district court has not misapplied the controlling legal standards in its evaluation of the evidence, its ultimate finding as well as the subsidiary findings upon which the ultimate finding necessarily depends, is subject to review on appeal under the clearly erroneous standard of Fed. R. Civ. P. 52(a).

COUNSEL: Frank J. Benasutti, of Philadelphia, Pennsylvania, argued for Appellant.

David J. Cushing, of Washington, District of Columbia, argued for Appellees. With him on the brief was Darryl Mexic.

JUDGES: Miller and Smith, Circuit Judges, and Re Judge. *

* The Honorable Edward D. Re. Chief Judge, United States Court of International Trade, sitting by designation.

OPINION BY: SMITH

OPINION: [*1573] SMITH, Circuit Judge.

In this patent case, ACS Hospital Systems, Inc. (ACS), appeals from a judgment of the U.S. District Court for the Western District of Pennsylvania, 564 F. Supp. 330, [*1574] holding U.S. patent No. 4,183,057, issued to Sonnenberg (the Sonnenberg patent), invalid as obvious under 35 U.S.C. § 103 (1976) and not infringed. Montefiore Hospital and Wells National Services Corp. (Wells) cross-appeal from the district court's denial of their motion for attorney fees. The judgment is reversed with respect to invalidity and affirmed with respect to noninfringement. With respect to Wells' cross-appeal from the denial of attorney fees, the [**2] judgment is affirmed.

Background

ACS's Sonnenberg patent claims a rental television system comprising a key operated actuating switch, an override switch, and a signal light to indicate that the override switch has been actuated. When the key switch is in the "on" position, the television operates normally. For rental use, the key switch is placed in the "off" position by a key operator. In order to rent the television, the viewer depresses the override switch which enables the television to operate normally without the necessity of turning on the key operated switch. When the override switch has been activated the indicator signal is illuminated, signaling that the television has been rented. Claim 1 is representative:

> A television system constructed for rental use, the television system comprising:
> actuating means including a key operated switch switchable between an off position for preventing normal operation of the television and an on position for enabling the television to be operated;
> override switching means capable of being switched from a normal position to an actuated position for overriding said key operated switch when in its off position and [**3] enabling the television to be operated; and said override switching means when switched in to [sic] its actuated position remains in said position until said key operated switch is switched into its on position; and
> indicating means for providing an indicating signal when said override switching means has been switched into its actuated position.

Validity

The trial court held the claims of the Sonnenberg patent invalid under section 103. While the trial court's opinion deals predominantly with infringement, the court purported to apply the standards articulated in *Graham v. John Deere Co.* n1 in determining the issue of validity. In concluding that the Sonnenberg patent is invalid under section 103, the district court relied on override switches generally and ACS's "COMPU-TEL" fully automated television rental system as prior art.

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n1 *Graham v. John Deere Co.*, 383 U.S. 1, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966).

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The court below stated that "the overriding of switches by providing [**4] an alternative path for current to actuate an appliance is a commonly practiced technique well known in the art prior to Sonnenberg's patent." It held that his claim 1 is therefore invalid as obvious. The trial judge adopted Wells' expert's description of ACS's COMPU-TEL system and held the Sonnenberg patent invalid as an attempt by ACS to "monopolize *all* systems of enabling a hospital patient to view television * * without the aid of an attendant." (Emphasis in original.) He commented that "the statutory presumption [of validity] of 35 U.S.C. 282 is entirely annihilated by the indisputable facts in the record."

Presumption of Validity

As an initial matter, we hold that the trial court's treatment of the presumption of validity is incorrect as a matter of law. HN1 The presumption is *never* annihilated, destroyed, or even weakened, regardless of [*1575] what facts are of record. n2 Rather, it is a clear statutory procedural device which assigns to the party asserting invalidity the burden of proving invalidity. n3

HN2 A patent shall be presumed valid. * * The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such [**5] invalidity. n4

The burden of persuasion is, and remains always, on the party asserting invalidity. n5 In the present case this error is not harmless. The district court's holding of invalidity has been shown, on the entire record, to have been reached on the basis of *both* clearly erroneous findings of fact and misapplication of the law. n6

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n2 *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534, 218 U.S.P.Q. (BNA) 871, 875-76 (Fed. Cir. 1983).

n3 *Id.*

n4 35 U.S.C. § 282 (1976).

n5 *Stevenson v. U.S. Int'l Trade Comm'n*, 67 CCPA 109, 612 F.2d 546, 551, 204 U.S.P.Q. (BNA) 276, 281 (1979); *Solder Removal Co. v. U.S. Int'l Trade Comm'n*, 65 CCPA 120, 582 F.2d 628, 632-33, 199 U.S.P.Q. (BNA) 129, 132-33 (CCPA 1978). *See also Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 220 U.S.P.Q. (BNA) 193 (Fed. Cir. 1983); *Medtronic, Inc. v. Cardiac Pacemakers, Inc.*, 721 F.2d 1563, 220 U.S.P.Q. (BNA) 97 (Fed. Cir. 1983); *Stratoflex*, 713 F.2d at 1534, 218 U.S.P.Q. (BNA) at 875-76; *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 773-74, 218 U.S.P.Q. (BNA) 781, 790 (Fed. Cir. 1983). [**6]

n6 *Cf. Medtronic*, 721 F.2d at 1566, 220 U.S.P.Q. (BNA) at 99 (errors in decisional approach considered harmless).

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Section 103

This court has in recent months issued a number of opinions addressing the analysis of obviousness under section 103 n7 and those opinions provide a comprehensive guide to analysis. We hold that the trial court's analysis of obviousness is inadequate under *Graham* n8 to sustain a holding of invalidity under section 103. However, the trial court's opinion contains sufficient findings of fact, supported in the record, to enable us to review the conclusion below that the Sonnenberg patent is invalid.

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n7 *In re Semaker*, 702 F.2d 989, 217 U.S.P.Q. (BNA) 1 (Fed. Cir. 1983); *Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 217 U.S.P.Q. (BNA) 193 (Fed. Cir. 1983); *Orthopedic Equip. Co. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 217 U.S.P.Q. (BNA) 1281 (Fed. Cir. 1983); *Chore-Time Equip., Inc. v. Cumberland Corp.*, 713 F.2d 774, 218 U.S.P.Q. (BNA) 673 (Fed. Cir. 1983); *Schenck, A.G. v. Nortron Corp.*, 713 F.2d 782, 218 U.S.P.Q. (BNA) 698 (Fed. Cir. 1983); *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 218 U.S.P.Q. (BNA) 865 (Fed. Cir. 1983); *Stratoflex*, 713 F.2d 1530, 218 U.S.P.Q. (BNA) 871. [**7]

n8 *Graham*, 383 U.S. at 17-18, 148 U.S.P.Q. (BNA) at 467, provides, in pertinent part:

"* * * [Section] 103 * * * HN3 lends itself to several basic factual inquiries. Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or non-obviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy. * * *"

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Scope and Content of the Prior Art.

In determining the scope and content of the prior art, the trial court found that override switches generally were well known in the art. It also found that ACS's COMPU-TEL system was within the prior art under section 102(g). The district court did [**8] not in its opinion rely on any other prior art reference in determining whether the claimed invention would have been obvious under section 103.

Five U.S. patents n9 are cited in the Sonnenberg patent as prior art. Further, the parties refer to the "Western New York Hospital" rental television system as prior art. While the trial judge made no mention in his opinion of these additional [*1576] references, on the basis of the record before us, they each constitute prior art relative to the Sonnenberg patent. We hold that the trial court's limited assessment of the prior art was clearly erroneous in that the court below failed to find that these additional references are within the scope and content of the prior art. These errors, however, have not been shown to have influenced the trial court's judgment in this case and, accordingly, we consider them harmless.

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n9 Norris, U.S. patent No. 2,856,474; Townsend, U.S. patent No. 3,188,384; Sargent, U.S. patent No. 3,335,421; Daniel, U.S. patent No. 3,631,444; and Kosco, U.S. patent No. 3,886,302.

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[**9]

Differences.

With respect to the differences between the claimed subject matter and the prior art, the district court gave claim 1 of the Sonnenberg patent an extremely broad construction. It adopted the opinion of Wells' expert that the COMPU-TEL system contains every feature of claim 1. Hence, the court below found no significant differences between the claimed subject matter and the prior art. We hold that finding to be clearly erroneous. In addition, that finding reflects an erroneous construction of the claims.

The trial court in its discussion of obviousness, rather than ascertaining the differences between the claimed subject matter and the prior art, focused on the differences between the Wells and the ACS systems. In so doing, it adopted Wells' expert's explanation of the differences between claim 1 and the Wells system -- differences relating to literal infringement, not validity. We conclude that the trial court erred in adopting Wells' expert's interpretation of claim 1.

Differences between the prior art and the claimed invention are apparent from the record. First, while override switches are used in a wide variety of applications, the examples of [**10] override switches cited by the district court are not relevant to the claimed subject matter as a whole -- television rental systems. The district court made

no attempt in its opinion to identify the differences between the override switching examples that it cited and the claimed subject matter.

Second, the record discloses that COMPU-TEL is a fully automated television rental system whereas the claimed invention involves human monitoring and control. While COMPU-TEL and the claimed invention both exhibit certain switching elements, the functions of the switching elements in the two systems are different. The fully automated operation of the COMPU-TEL system does not involve overriding a locked key switch. The patient switch in the COMPU-TEL system functions to actuate the television as well as to initiate billing. The override switching means claimed in the Sonnenberg patent, on the other hand, functions to provide an alternative current path to the locked key switch and to actuate the indicator light.

Third, the prior art of record that the court did not discuss also differs significantly from the claimed subject matter. The five patent references cited in the Sonnenberg [**11] patent involve a variety of lock, metering, and control systems. None of them, however, employs an override switching mechanism to overcome a key operated actuating switch. The Western New York Hospital system involves a three position key switch. Yet, that system differs from the claimed subject matter in that it too does not employ override switching means.

Hence, we hold the trial court's assessment, that there are no differences between the claimed subject matter and the prior art, was clearly erroneous.

Level of Ordinary Skill and Secondary Considerations.

Additionally, the court below made no express finding with respect to the level of ordinary skill in the art. The trial court's analysis, however, clearly indicates that the level of skill was considered to be quite low. We interpret the court's findings as fixing the level of ordinary skill in the art as that of a layman. That finding has not [*1577] been shown to be clearly erroneous. The court made no findings with respect to secondary considerations.

Claim Construction.

As noted above, the trial court's opinion reflects an extremely broad construction of the claims. Contrary to the [**12] district court's construction of the claims, the Sonnenberg patent does not claim "*all* systems of enabling a hospital patient to view television normally under his own power without the aid of an attendant." (Emphasis in original.) The court ignored express claim limitations governing the function of the switching means.

HN4 Claims are to be read and construed in light of the specification and the prosecution history of the patent. n10 Further, claims should be so construed, if possible, as to sustain their validity. n11 Applying these principles, the claims of the Sonnenberg patent should be given a far more limited construction than that given by the district court in holding the claims invalid. The claims are limited to a system in which override switching means function to override a key switch when in its "off" position, enabling the television to operate normally. The Sonnenberg patent does not claim "*all*" hospital rental systems capable of operation without an attendant. Claim construction is a question of law. n12 We hold that the trial court's construction of the claims is incorrect as a matter of law.

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n10 *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1570-71, 219 U.S.P.Q. (BNA) 1137, 1140-41 (Fed. Cir. 1983); *Autogiro Co. v. United States*, 181 Ct. Cl. 55, 384 F.2d 391, 397-99, 155 U.S.P.Q. (BNA) 697, 702-04 (1967). [**13]

n11 *Carman Indus., Inc. v. Wahl*, 724 F.2d 932, 937 n.5, 220 U.S.P.Q. (BNA) 481, 485 n.5 (Fed. Cir. 1983); *Klein v. Russell*, 86 U.S. (19 Wall.) 433, 466, 22 L. Ed. 116 (1874); *Turrill v. Michigan S. & N.I. R.R.*, 68 U.S. (1 Wall.) 491, 510, 17 L. Ed. 668 (1864).

n12 *Autogiro*, 384 F.2d at 397-99, 155 U.S.P.Q. (BNA) at 702-04; *LaSalle v. Carlton's Laydown Serv., Inc.*, 680 F.2d 432, 216 U.S.P.Q. (BNA) 276 (5th Cir. 1982); *Studiengesellschaft Kohle mb H v. Eastman Kodak Co.*, 616 F.2d 1315, 206 U.S.P.Q. (BNA) 577 (5th Cir.), *cert. denied*, 449 U.S. 1014, 66 L. Ed. 2d 473, 101 S. Ct. 573, 208 U.S.P.Q. (BNA) 88 (1980).

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Obviousness.

Turning now to the determination of obviousness under section 103, we conclude that none of the references, either alone or in combination, would have disclosed or suggested to one of ordinary skill in the art the use of override switching means in a television rental system. The trial court's heavy reliance on the widespread use of override switches appears to be no more than hindsight reconstruction of the claimed invention. The [**14] court below identified no source, other than the Sonnenberg patent itself, for the suggestion to use override switching means in a television rental system.

HN5 Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. n13 Under section 103, teachings of references can be combined *only* if there is some suggestion or incentive to do so. n14 The prior art of record fails to provide any such suggestion or incentive. Accordingly, we hold that the court below erred as a matter of law in concluding that the claimed invention would have been obvious to one of ordinary skill in the art under section 103.

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n13 *Orthopedic Equip. Co.*, 702 F.2d at 1012, 217 U.S.P.Q. (BNA) at 199; *cf. In re Samour*, 571 F.2d 559, 563, 197 U.S.P.Q. (BNA) 1, 4 (CCPA 1978) (noting the rule in the § 103 context and declining to extend that rule to § 102(b) rejections); *Corometrics Medical Sys., Inc. v. Berkeley Bio-Engineering, Inc.*, 193 U.S.P.Q. (BNA) 467, 475 (N.D. Cal. 1977).

n14 *In re Rinehart*, 531 F.2d 1048, 189 U.S.P.Q. (BNA) 143 (CCPA 1976); *In re Regel*, 526 F.2d 1399, 188 U.S.P.Q. (BNA) 136 (CCPA 1975); *In re Avery*, 518 F.2d 1228, 186 U.S.P.Q. (BNA) 161 (CCPA 1975); *In re Imperato*, 486 F.2d 585, 179 U.S.P.Q. (BNA) 730 (CCPA 1973); *In re Andre*, 52 CCPA 1019, 341 F.2d 304, 144 U.S.P.Q. (BNA) 497 (CCPA 1965).

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[*1578] *Infringement*

The trial court found that the Wells system does not infringe the claimed invention, either literally or under the doctrine of equivalents. Once again adopting the testimony of Wells' expert, the court below found that "the Wells system does not contain the element of overriding a locked switch." The district court also found differences between the ACS system and the Wells device with respect to the mechanism and circuitry of the actuating switch as well as with respect to the indicator light.

These latter findings, however, will not support a finding of no infringement. The claims of the Sonnenberg patent are not limited to a specific switching mechanism or to specific indicator light circuitry. The district court appears to have compared the Wells system with ACS's commercial product, rather than with the claims of the Sonnenberg patent. HN6 Infringement is determined on the basis of the claims, not on the basis of a comparison with the patentee's commercial embodiment of the claimed invention.

The district court's failure to supply more comprehensive findings of fact compounds the difficulty of appellate review, particularly in view of the [**16] complexity of the technical subject matter of this appeal. HN7 Findings of fact are to be construed liberally in support of a judgment. Confined to the trial court's limited findings, we are forced to draw from the facts found those inferences that are necessary to support the ultimate finding that the Sonnenberg patent is not infringed by Wells. n15

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n15 5A J. MOORE, J. LUCAS, MOORE'S FEDERAL PRACTICE para. 52.06[1] (2d ed. 1984).

- - - - - - - - - - - - End Footnotes- - - - - - - - - - - - - -

In this endeavor we are not ourselves finding those facts which the trial court failed to set out for us. As an appellate court, we lack the power to perform that exercise. HN8 Where the trial court fails to make findings, the judgment will normally be vacated and the action remanded for appropriate findings to be made. n16 Where a full understanding may be had without the aid of separate findings, however, we recognize a narrow exception to that general rule. n17

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n16 *Pullman-Standard v. Swint*, 456 U.S. 273, 292 n.22, 72 L. Ed. 2d 66, 102 S. Ct. 1781 (1982); 5A MOORE'S FEDERAL PRACTICE para. 52.06[2]. [**17]

n17 *See* 5A MOORE'S FEDERAL PRACTICE para. 52.06[2] n.4 and cases cited therein.

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HN9 The ultimate finding of fact in a case, whether initially by the trial court, or as affirmed on appeal, rests on the same underpinnings, *i.e.*, the necessary subsidiary facts, supported by evidence of record, that lead to that ultimate finding. Where the district court has not misapplied the controlling legal standards in its evaluation of the evidence, its ultimate finding as well as the subsidiary findings upon which the ultimate finding necessarily depends, is subject to review on appeal under the clearly erroneous standard of Fed. R. Civ. P. 52(a). n18 We examine the record in order to review the trial court's judgment, and the findings it made or necessarily had to have made to support that judgment and, thus, to conclude the controversy at this stage without unnecessary further expenditure of judicial resources, if possible.

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n18 *Cf. Pullman-Standard*, 456 U.S. 273, 72 L. Ed. 2d 66, 102 S. Ct. 1781.

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[**18]

The Sonnenberg Claims.

The Sonnenberg patent claims a rental television system having key operated actuating means capable of being overridden by an override switching means. An indicating means signals that the override switching means has been actuated. Once overridden, the switches and the indicator light remain in their overridden positions until the key operated switch is switched on, resetting the override switching and indicating means.

The Accused Infringing Device.

The Wells device also contains each of the three physical elements of claim 1 of [*1579] the Sonnenberg patent: (1) a key operated actuating switch; (2) a remote control

actuating switch; and (3) an indicator light. The district court, however, found that the Wells device does not contain the claimed limitation of overriding a locked switch -- a difference in function.

The Wells device is a modified version of a standard hospital/hotel/motel television receiver. The keylock in the Wells system actuates 5 switches: S1XA; S1XB; S1B; S1C; and S1D [Fig. 1].

[SEE ILLUSTRATION IN ORIGINAL]
In the Wells device, the jumper wires, provided by the manufacturer on switches S1B and [**19] S1C, are not removed. [Fig. 2.]

[SEE ILLUSTRATION IN ORIGINAL]
Switches S1B and S1C are shorted out by those jumper wires, rendering those switches electrically inoperable.

Additionally, switch S1D [Fig. 1] is "replaced" by relay RL-2 [Fig. 3] of the Wells remote control circuit.

[*1580] [SEE ILLUSTRATION IN ORIGINAL]

Relay RL-2 is connected in parallel with switch S1D and one of the leads to switch S1D is cut between switch S1D and the connection of the lead to relay RL-2 [Fig. 3]. Thus, the circuit through switch S1D is broken, rendering that switch electrically inoperable.

Unlike switch S1D which it replaces, relay RL-2 is not controlled by the key switch. Rather, switch S1 [Fig. 3], located on the remote control unit, operates relay RL-2 in the Wells device. When S1 is not depressed, relay RL-2 remains normally closed. When switch S1 is depressed, the coil in relay RL-2 is energized causing relay RL-2 to open. Similarly, switch S1D, which relay RL-2 replaces, was normally closed when the television was not rented and was opened by turning the key switch to rent the television.

Switches S1B, S1C, and S1D, therefore, are disabled in the [**20] Wells device. The key switch operates only two switches -- S1XA and S1XB [Fig. 1] -- which control the delivery of power to the television receiver. When these switches are closed [positions 2 and 3] [Table 1], power is delivered to the tuner; when these switches are open [position 1] [Table 1], the circuit is broken and no power reaches the tuner.

[*1581] [SEE ILLUSTRATION IN ORIGINAL]

As manufactured, when the key switch of a standard receiver is in position 2 [Table 1], switch S1D is open and the television operates normally. Position 2 functions as an "on" setting in the standard receiver. In the Wells device, however, switch S1D [Table 1] has been disconnected and it has been replaced by relay RL-2. Relay RL-2 cannot be opened by manipulation of the key switch, as was switch S1D. Thus, the receiver cannot be actuated merely by turning the key switch to position 2 in the Wells device. n19 Switch S1 opens relay RL-2. The Wells receiver can be made fully operable only by depressing switch S1 [Fig. 3] while master on-off switches S1XA and S1XB are closed -- position 2 or 3 [Table 1].

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n19 It appears that had RL-2 and S1D been wired in series, instead of in parallel with S1D disabled, the Wells device would exhibit the claimed "on" function.

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When the key switch is in position 1, power is interrupted and depressing actuating switch S1 will not actuate the receiver. The Wells key switch performs the same function in position 2 as in position 3. In both of those positions, while power is supplied to the tuner, the actuating switch S1 must be depressed in order to actuate the television. Thus, switch S1 does not override the key switch of the Wells device. n20 Switch S1 and the key switch are electrically independent in the Wells device [Fig. 4].

- - - - - - - - - - - - - - Footnotes - - - - - - - - - - - - - -

n20 Our assessment of the operation of the Wells device is based on the trial court's findings and on the documentary and testimonial evidence of record. It appears that only switches S1XA and S1XB are controlled by the key switch. Thus, our analysis supports the trial judge's implication that there is no functional difference between positions 2 and 3 of the key switch. The above analysis assumes that the key switch does not operate some third circuit that is actuated in either position 2 or position 3, but not both. We are aware of no evidence that such a third circuit fulfills the role of the key switch and is in turn overridden by switch S1.

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[*1582] [SEE ILLUSTRATION IN ORIGINAL]

In summary, the Wells device exhibits three modes of operation: (1) off -- locked out (switches S1XA and S1XB open); (2) rentable -- key position 2 or 3 and S1 not actuated (switches S1XA and S1XB closed and switch S1 open); and (3) rented -- key position 2 or 3 and S1 actuated (switches S1XA and S1XB closed and switch S1 closed). Normal operation of the Wells device can be achieved *only* by depressing S1 *while* the power is switched on (key switch position 2 or 3). The invention claimed in the Sonnenberg patent, on the other hand, also exhibits three modes of operation: (1) "off" -- rentable (override switch not actuated); (2) "on" -- rented (override switch actuated); and (3) "on" -- key operation (key switch turned on and override switch not actuated).

On the basis of our examination of the record we infer that the district court necessarily found the following relative to the Wells device: (1) switches S1B, S1C, and S1D are disabled; (2) the key switch controls only switches S1XA and S1XB -- the master on-off switch; and (3) the receiver can be actuated only by depressing S1 while the key switch is in either position 2 [**23] or 3 (so that switches S1XA and S1XB are closed).

Literal Infringement.

These implied findings lead inexorably to the district court's express finding that the Wells device lacks the claimed limitation of overriding a locked key switch. Further, these findings indicate that the Wells device does not exhibit the claimed "on" key switch position.

Both the "on" and "off" positions recited in claim 1 correspond to the "on" positions [positions 2 and 3] of the key switch in the Wells device. The Wells device cannot be operated normally through the key switch alone, as is required by claim 1. Rather, switch S1 must be depressed in conjunction with power being supplied to the receiver through the key switch. Hence, on the basis of the record before us, we conclude that the district court's finding, that Wells does not literally infringe the claims of the Sonnenberg patent, is not clearly erroneous.

Doctrine of Equivalents.

While the district court purported to apply the standard articulated in *Graver Tank & Manufacturing Co. v. Linde Air Products Co.*, n21 it entered no findings on the issue of equivalence: whether the Wells device performs substantially [**24] the same function as the claimed invention in substantially the same way to obtain substantially the same result. n22 Yet, the court clearly implied that Wells does not infringe the Sonnenberg patent under the doctrine of equivalents and entered judgment to that effect.

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n21 *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 607-09, 94 L. Ed. 1097, 70 S. Ct. 854 (1950).

n22 *Id.* at 608; *Sanitary Refrigerator Co. v. Winters*, 280 U.S. 30, 42, 74 L. Ed. 147, 50 S. Ct. 9 (1929).

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We infer that the district court necessarily found that the Wells device, lacking the claimed function of overriding a locked key switch, does not function in substantially the same way as the claimed invention. [*1583] That inference is supported by the record. Accordingly, we conclude that the district court's finding, that the Wells device does not infringe the Sonnenberg patent under the doctrine of equivalents, is not clearly erroneous.

Hence, we affirm in part the judgment of the district court [**25] insofar as it relates to the finding that the Wells device does not infringe the claims of the Sonnenberg patent, either literally or under the doctrine of equivalents.

Attorney Fees

The trial judge found that this is not an exceptional case and denied Wells' request for attorney fees. In order to prevail on its cross-appeal, Wells must establish that the trial judge abused his discretion in this regard and not merely, as Wells' attorneys contend, that the trial judge committed clear error. Wells has not demonstrated the requisite abuse of discretion, although it attempts to do so by demonstrating alleged fraudulent conduct by ACS before the Patent and Trademark Office. Fraud has not been shown. Nor have other facts been established that would demonstrate that the trial judge abused his discretion in finding that this case is not exceptional. Thus, we affirm the district court's denial of Wells' motion for attorney fees.

Conclusion

In summary, we hold that the district court committed both clear errors of fact and errors of law with respect to its resolution of the validity issue. The district court's conclusion that the Sonnenberg patent is invalid under section [**26] 103 is incorrect as a matter of law. We conclude that the trial court's finding, that Wells does not infringe the claims of the Sonnenberg patent, either literally or under the doctrine of equivalents, is not clearly erroneous. Additionally, we hold that the trial judge did not abuse his discretion in denying Wells' motion for attorney fees.

AFFIRMED IN PART AND REVERSED IN PART.

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*681 F.2d 792, *; 1982 CCPA LEXIS 126, **; 215 U.S.P.Q. (BNA) 569*

IN RE ROLAND N. FRACALOSSI AND MARK T. WAJER

Appeal No. 81-609.

UNITED STATES COURT OF CUSTOMS AND PATENT APPEALS

681 F.2d 792; 1982 CCPA LEXIS 126; 215 U.S.P.Q. (BNA) 569

Oral argument on March 8, 1982 June 24, 1982

PRIOR HISTORY: [**1]

Serial No. 905,544.

CASE SUMMARY

PROCEDURAL POSTURE: Appellants opposed decision from the Patent and Trademark Office Board of Appeals affirming rejection of appellants' patent claims under 35 U.S.C.S. § 103.

OVERVIEW: The Patent and Trademark Office (PTO) Appeal Board rejected appellants' patent application. Appellants' claims were directed to a composition that produced a dripless char when subjected to combustion temperature. The court held that the invention was properly rejected. The prior art disclosed the claimed invention. No additional evidence was introduced by appellants. Because the claimed invention lacked novelty, it was obvious.

OUTCOME: Court upheld decision of the appeal board rejecting appellants' claims because the claimed invention was disclosed in the prior art, and appellants failed to provide any evidence establishing novelty in the invention. Lack of all novelty evidenced obviousness.

CORE TERMS: foam, polyol, retardant, flexible, flame, blowing, obviousness, composition, unreacted, novelty, invention, dripless, teaching, foam-forming, temperature, char, disclosure, rigid, diisocyanate, polyurethane, combustion, char-forming, anticipated, declaration, subjected, disclose, suitable, fire retardant, patent, decomposition

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Patent Law > Claims & Specifications > Enablement Requirement > General Overview
Patent Law > Inequitable Conduct > General Overview
Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > Appeals
HN1 An appellant patent-applicant bears the burden of introducing evidence that prior art lacks an enabling disclosure.

Patent Law > Anticipation & Novelty > General Overview
Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > Appeals
Patent Law > Nonobviousness > General Overview
HN2 Evidence establishing lack of all novelty in the claimed invention necessarily evidences obviousness.

COUNSEL: *A. W. Breiner* and *Theodore A. Breiner,* of Arlington, VA, attorneys for appellants.

JOSEPH F. Nakamura, Solicitor, and *Harris A. Pitlick,* Assistant Solicitor, of Washington, D.C., attorneys for the Patent and Trademark Office.

OPINION BY: MARKEY

OPINION: [*792]

Before MARKEY, Chief Judge, RICH, BALDWIN, MILLER, and NIES, Associate Judges.

MARKEY, Chief Judge.

The decision of the Patent and Trademark Office Board of Appeals (board) sustaining the rejection of claims 1, 2, 4, 5, 7-16, 18 and 19 under 35 USC 103 is affirmed.
The Invention

The appealed claims are directed to a composition comprising the combination of an unreacted polyol and a flame retardant in a flexible polyurethane foam. That composition is said to produce a substantially dripless char when subjected to combustion temperature. Claim 1 is illustrative:

1. A flexible polyurethane foam comprising the foam-forming reaction product of a reactive poly ol and a diisocyanate and including uniformly contained in said foam a flame retardant agent and an unreacted polyol selected from the group consisting of a polyol having the empirical formula of (C[6]H[10]O[5])[x] [**2] wherein X is in excess of about 60 and methylol melamine containing hydroxyl groups substantially unreacted with said diisocyanate, said flame retardant agent and unreacted polyol being present in an amount sufficient to inhibit flaming and to form a substantially dripless char when said foam is subjected to combustion temperatures.
Prior Art

The sole reference is U.S. Patent No. 3,753,933 issued to Olstowski et al. (Olstowski) on August 21, 1973. Olstowski teaches both rigid and flexible polyurethane foams derived from the foam-forming reaction product of a reaction polyol, a diisocyanate, and a blowing agent. The blowing agent comprises a solid particulate substance having a particular particle size and surface area and substantially insoluble in either the polyol, diisocyanate, or both. The blowing agent is further characterized as having a decomposition temperature above the exothermic temperature of the reaction of polyol with diisocyanate.

Olstowski states that the end use of the foam product often suggests the type of blowing agent to be used. For example, if [*793] the foam is required to possess magnetic

properties, blowing agents such as powdered iron or [**3] other powerdered alloys are suggested.If the foamed product is to be used as an abrasive wheel, the use of blowing agents such as ultrafine alumina or silicon carbide powders are suggested. Included within the materials disclosed as suitable blowing agents are the unreacted polyols claimed by applicant.

Olstowski further discloses the use of flame retardant agents in the disclosed compositions.
Wajer Declaration

Co-inventor Wajer described in a declaration the different burn characteristics of rigid and flexible polyurethane foams, comparing with rigid foams the flexible foams corresponding to the present invention.Accompanying experimental data showed that the present flexible foams, unlike rigid foams, do not form a substantially dripless char when subjected to combustion temperatures unless both a flame retardant agent and an unreacted polyol are present. Wajer distinguished U.S. Patent No. 3,956,202 issued to Iwasaki (no longer a basis for rejection) as disclosing a rigid, not a flexible foam. Wajer concluded that nothing in Iwasaki would lead him to believe that the dripping of flexible foams could be reduced by including a combination of flame retardant and corn starch [**4] (an unreacted polyol) in the foam formulation.
The Board

The board rejected appellants' argument that the polyol, described as a blowing agent by Olstowski, must necessarily be transformed in the course of the foam-forming reaction and could not therefore be present in the reaction product in suitable amounts. Based on Olstowski's dislosure of an insoluble blowing agent, a requirement that the blowing agent have a decomposition temperature exceeding the exothermic temperature of the reaction, use of a blowing agent within the claimed concentration levels, and the inclusion of obviously non-reactive materials among suggested blowing agents, the board reasoned that Olstowski disclosed a blowing agent that is not completely destroyed in the foam-forming reaction but has at least portions remaining in the foam product.

The board concluded that appellants' recognition that use of a polyol of which portions do not react and a flame retardant in a flexible foam would enable production of a dripless char cannot be the basis for patentable distinctness, where the artisan would be taught by Olstowski to use a polyol of which portions do not react and a flame retardant. The board considered [**5] the Wajer declaration of no probative value.

Opinion

Appellants acknowledge that the claimed flexible polyurethane foam is derived from the foam-forming reaction product of a reactive polyol and a diisocyanate, as is conventional. Appellants further acknowledge that Olstowski discloses a foam-forming reaction product which may include a flame retardant and, as a blowing agent, a polyol of the type recited in the appealed claims.

Appellants argue that the polyols used as blowing agents by Olstowski do not survive the foam-forming reaction and therefore are not the claimed "unreacted" polyols and cannot produce the desired char-forming characteristics in the final flexible foam product. That argument raises the question of whether Olstowski is an enabling disclosure of the claimed invention. HN1 Appellants bear the burden of introducing evidence that Olstowski lacks an enabling disclosure. In re Baxter, 656 F.2d 679, 685, 210 USPQ@ 795, 801 (CCPA 1981); In re Jacobs, 50 CCPA 1316, 1319, 318 F.2d 743, 745, 137 USPQ 888, 889 (1963). No such evidence was presented. Appellants' non-enablement argument must therefore fail.

Appellants' argument concerning survivability of Olstowski's [**6] polyols may also be considered as raising the question of whether Olstowski's disclosure is sufficient to support a rejection under 35 USC 103. We agree with the board, however, that considerations described by Olstowski respecting selection and characteristics of particular materials for suitable blowing [*794] agents establish that Olstowski does sufficiently disclose a flexible foam product containing an unreacted polyol component. We also detect no error in the board's conclusion that Olstowski discloses the use of a flame retardant agent in any of his foams where a flame retardant foam is desired. n1 Appellants have neither alleged nor demonstrated that Olstowski fails to disclose the proper relative amounts of polyol and flame retardant to be added to the composition to produce a dripless flexible foam.

n1 It is axiomatic that a reference must be considered in its entirety, and it is well established that the disclosure of a reference is not limited to specific working examples contained therein. E.g., In re Lamberti, 545 F.2d 747, 750, 192 USPQ 278, 280 (CCPA 1976). Olstowski is prior art not only for the teaching of the specific embodiment recited but for what it fairly teaches to the skilled in the art. In re Boe, 53 CCPA 1079, 1082, 355 F.2d 961, 964, 148 USPQ 507, 510 (1966). One skilled in the art could hardly be expected to ignore Olstowski's teaching of the use of fire retardant agents where, as here, the combustion properties of the foam product are the primary concern.

To show unexpected results or for that matter any difference at all between the claimed invention and the closest prior art, appellants would have had to compare the claimed invention with the flexible foam of Olstowski, including the addition of a fire retardant as taught by Olstowski. In re Boe, supra. No such comparison was made. [**7]

We therefore conclude that Olstowski's teachings result in the claimed foam. Thus the claimed invention lacks novelty. Though the PTO spoke in terms of obviousness, the lack of novelty from the claimed invention is a fact. Moreover, lack of novelty is the ultimate of obviousness. If, indeed, a dripless characteristic of this old foam was an unobvious discovery, that discovery would not entitle appellants to claim the foam.

As the examiner correctly said, "This property... does not serve to distinguish the composition from Olstowski's." (emphasis added). An old composition cannot be converted into an unobvious composition simply by inept references to obviousness. Nor can that be done through discussion of the concept of "Inherency", which is a fact question. That the rejection is here described as one under § 103 is not controlling, for it is not in this case rebuttable by evidence. Here we have the ultimate obviousness -- lack of novelty. To recognize that fact is not to replace the rejection with a new one based on anticipation.Though the composition might have been obvious, though not anticipated, it cannot have been anticipated and not have been obvious. Thus HN2 evidence [**8] establishing lack of all novelty in the claimed invention necessarily evidences obviousness.As we noted in In re Pearson, 494 F.2d 1399, 1402, 181 USPQ 641, 644 (CCPA 1974):

[T]his court has sanctioned the practice of nominally basing rejections on § 103 when, in fact, the actual ground of rejection is that the claims are anticipated by the prior art. See In re Dailey, 479 F.2d 1398, 178 USPQ 293 (CCPA 1973). The justification for this sanction is that a lack of novelty in the claimed subject matter, e.g., as evidenced by a complete disclosure of the invention in the prior art, is the "ultimate or epitome of obviousness." In re Kalm, 54 CCPA 1466, 1470, 378 F.2d 959, 962, 154 USPQ 10, 12 (1967).
In sum, and whatever the language of discussion, the facts present an irrebuttable case of obviousness of product claims.

Though compositions of the same structure are expected to have the same properties, n2 appellants have argued that the claimed char-forming property would not be inherent in the Olstowski composition. n3 Appellants, however, have presented no evidence to support that argument, nor could they in view of Olstowski's disclosure of the same composition.

n2 In re Gyurik, 596 F.2d 1012, 1018, 201 USPQ 552, 556 (CCPA 1979); In re Wilder, 563 F.2d 457, 460, 195 USPQ 426, 429 (CCPA 1977).

n3 See In re Hoch, 57 CCPA 1292, 1296, 428 F.2d 1341, 1344, 166 USPQ 406, 409 (1970). [**9]

The Wajer declaration, while demonstrating differences between the char-forming characteristics of flexible and rigid foams nowhere compares the flexible foam of [*795] Olstowski with that claimed. That declaration merely demonstrates that flexible foam must contain both an unreacted polyol and a flame retardant to form a substantially dripless char. Nowhere does Wajer allege that the foam of Olstowki does not contain unreacted polyol or that a dripless char would be unexpected when the composition of Olstowski (containing both the polyol and the flame retardant) is subjected to similar conditions. At most, appellants have asserted that when one who prepares one of the compositions disclosed by Olstowski, and subjects it to combustion, the resulting char will not drip.

Accordingly, the decision of the board sustaining the rejection of the claims is affirmed.

AFFIRMED

CONCUR BY: MILLER

CONCUR: MILLER, J., with whom BALDWIN, J., joins, concurring.

The only rejection made below was for obviousness (35 USC 103). The majority affirms the section 103 obviousness rejection because it concludes that there is a "lack of novelty." However, the statutory language makes clear that "lack [**10] of novelty" is not a basis for a section 103 rejection. n1 To add a rejection for "lack of novelty" for the first time on appeal would deny appellants administrative due process. See, e.g., In re Waymouth, 486 F.2d 1058, 1061, 179 USPQ 627, 629 (CCPA 1973); In re Arkley, 59 CCPA 804, 809, 455 F.2d 586, 589, 172 USPQ 524, 527 (1972). Accordingly, the court should address only the issue of patentability raised below--the

obviousness of the claimed foams in view of Olstowski's teachings.

n1 35 USC 103 provides in part: "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if...." (Emphasis supplied.)

The majority opinion relies on In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974) as justification for affirming the section 103 rejection on the basis of "lack of novelty," but omits from its quotation the following footnote, which underscores the crucial difference between that case and this one:

The record establishes that appellant was fully aware of the ground of rejection being put forth regardless of its statutory basis. Furthermore, the board, in affirming the rejection under § 103, [**11] did not in effect make a new rejection under § 102 as occurred in In re Echerd, 471 F.2d 632, 176 USPQ 321 (CCPA 1973).
Id. at 1402 n.2, 181 USPQ at 644 n.2.

Lack of novelty was never argued below and is not mentioned in the briefs on appeal. Rather, the board held that it would have been obvious for a person of ordinary skill in the art to select Olstowski's example 5 teaching of a flexible foam containing unreacted polyol and to combine it with a flame retardant based on Olstowski's suggestion (in the context of what additives may be added to any of his foams) that a flame retardant may also be desirable. There was no mention that Olstowski anticipates the appealed claims. The "closest prior art" was never defined as Olstowski's example 5 foam plus flame retardant. The board stated: "The additional presence of a flame retardant clearly is suggested by Olstowski (column 4, lines 7-11) and, although this is not specifically exemplified, it, nevertheless, manifestly is obvious from patentee's teaching." (Emphasis supplied.) Similarly, the examiner stated that there was "ample motivation to employ the additives together for their expected flameproofing and blowing utilities...." [**12]

Appellants may or may not have been able to overcome a "lack of novelty" rejection with appropriate arguments (see, e.g., the considerations set forth in In re Arkley, supra at 807, 455 F.2d at 587, 172 USPQ at 526, and In re Ruschig, 52 CCPA 1238, 1249-51, 343 F.2d 965, 973-75, 145 USPQ 274, 281-82 (1965)). However, in reviewing a rejection based solely on obviousness, such as the one on appeal, it is always appropriate to consider objective evidence of unobviousness. In re Arkley, supra. Although appellants' evidence is insufficient in this [*796] case, I am troubled by the majority opinion's suggestion that the section 103 rejection "is not in this case rebuttable by evidence" and that "the facts present an irrebuttable case of obviousness of product claims." Aside from the statutory problem with an irrebutable section 103 case (Graham v. John Deere Co., 383 U.S. 1, 17 (1966)), I am not persuaded that the prima facie case of obviousness here could never have been overcome. n2 Finally, because the so-called "secondary considerations" relevant to a case of prima facie obviousness are not considered for purposes of determining anticipation, it does not follow that every technically [**13] anticipated invention would also have been obvious. See In re Sivaramakrishnan, F.2d , 213 USPQ 441 (CCPA 1982) (CCPA notes that board reversed section 103 rejection because of comparative tests, while entering section 102 rejection of same claims).

n2 For example, appellants might be able to show that Olstowski's teaching of equivalence among the five types of particle-containing foams is wrong, e.g., that only the polyol-containing foams display the char-forming property.

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*802 F.2d 1367, *; 1986 U.S. App. LEXIS 20347, **; 231 U.S.P.Q. (BNA) 81*

HYBRITECH INCORPORATED, Appellant, v. MONOCLONAL ANTIBODIES, INC., Appellee

Appeal No. 86-531

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

802 F.2d 1367; 1986 U.S. App. LEXIS 20347; 231 U.S.P.Q. (BNA) 81

September 19, 1986

PRIOR HISTORY: [**1] Appealed from: U.S. District Court for the Northern District of California. Judge Conti.

DISPOSITION: Reversed and Remanded.

CASE SUMMARY

PROCEDURAL POSTURE: Plaintiff appealed a judgment of the United States District Court for the Northern District of California in favor of defendant in plaintiff's infringement action. The district court held that all claims of plaintiff's patent were invalid for anticipation under 35 U.S.C.S. § 102(g), for obviousness under 35 U.S.C.S. § 103, and under 35 U.S.C.S. § 112.

OVERVIEW: Plaintiff, a corporation in the business of developing diagnostic kits, sued defendant corporation, alleging that the manufacture and sale of defendant's diagnostic kits infringed plaintiff's patent with claims defining a variety of sandwich assays using monoclonal antibodies. The district court ruled in favor of defendant, holding that all claims of plaintiff's patent were invalid for anticipation under 35 U.S.C.S. § 102(g), for obviousness under § 103, and under 35 U.S.C.S. § 112. The court reversed, holding that although some of plaintiff's inventor's

laboratory notebooks were not witnessed until a few months to one year after their writing due to plaintiff's inexperience as a start-up company, the notebooks were still corroborative and clearly showed conception of the claimed invention before others. Furthermore, the large number of references relied upon by the district court to show obviousness skirted around but did not as a whole suggest the claimed invention.

OUTCOME: The court reversed the judgment of the district court holding plaintiff's patent invalid in all respects, since the district court's decision was based on clearly erroneous factual findings, and remanded the matter for determination of plaintiff's claim of infringement.

CORE TERMS: monoclonal antibodies, antibody, invention, antigen, assay, sandwich, affinity, monoclonal, notebook, kit, labelled, patent, fluid, obviousness, antigenic, polyclonal, reduction, epitope, prior art, carrier, immunoassay, laboratory, hybridoma, liters, solid, mole, subject matter, diagnostic, disclose, cell

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Civil Procedure > Appeals > Reviewability > Preservation for Review

HN1 See Fed. R. Civ. P. 52(a).

Civil Procedure > Appeals > Standards of Review > Clearly Erroneous Review
Criminal Law & Procedure > Appeals > Standards of Review > General Overview
Patent Law > Jurisdiction & Review > Standards of Review > General Overview

HN2 Findings of the district court may be reversed only if clearly erroneous. A finding is clearly erroneous when, although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed.

Civil Procedure > Appeals > Standards of Review > Clearly Erroneous Review
Patent Law > Jurisdiction & Review > Standards of Review > General Overview

HN3 If documents or objective evidence contradict a witness's story, clear error may be found even in a trial court's finding purportedly based on a credibility determination.

Evidence > Procedural Considerations > Burdens of Proof > Clear & Convincing Proof
Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview
Patent Law > Infringement Actions > Defenses > Patent Invalidity > Validity Presumption

HN4 Under 35 U.S.C.S. § 282, a patent is presumed valid, and the one attacking validity has the burden of proving invalidity by clear and convincing evidence. Notwithstanding that the introduction of prior art not before the examiner may facilitate the challenger's meeting the burden of proof on invalidity, the presumption remains intact and on the challenger throughout the litigation, and the clear and convincing standard does not change.

Patent Law > Anticipation & Novelty > Invention

HN5 35 U.S.C.S. § 102(g) states that a person shall be entitled to a patent unless before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. Section 102(g) relates to prior inventorship by another in this country and retains the rules governing the determination of priority of invention.

Patent Law > Anticipation & Novelty > General Overview
Patent Law > Date of Invention & Priority > Conception Date

HN6 See 35 U.S.C.S. § 102(g).

Civil Procedure > Appeals > Standards of Review > Clearly Erroneous Review
Patent Law > Anticipation & Novelty > General Overview
Patent Law > Jurisdiction & Review > Standards of Review > General Overview

HN7 Reduction to practice, and conception as well, is a legal determination subject to review free of the clearly erroneous standard. Findings of fact supporting that legal conclusion are reviewed under the clearly erroneous standard.

Patent Law > Anticipation & Novelty > General Overview
Patent Law > Date of Invention & Priority > General Overview

HN8 Conception is the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice. Actual reduction to practice requires that the claimed invention work for its intended purpose, and constructive reduction to practice occurs when a patent application on the claimed invention is filed.

Patent Law > Anticipation & Novelty > Fact & Law Issues

HN9 It is axiomatic that for prior art to anticipate under 35 U.S.C.S. § 102 it has to meet every element of the claimed invention, and that such a determination is one of fact.

Civil Procedure > Appeals > Standards of Review > Clearly Erroneous Review
Patent Law > Claims & Specifications > Enablement Requirement > General Overview
Patent Law > Nonobviousness > Elements & Tests > General Overview

HN10 An obviousness determination under 35 U.S.C.S. § 103, whether the claimed invention would have been obvious at the time the invention was made, is reviewed free of the clearly erroneous standard. However, the underlying factual inquiries -- scope and content of the prior art, level of ordinary skill in the art, and differences between the prior art and the claimed invention -- integral parts of the subjective determination involved in § 103, are reviewed under that standard. Objective evidence such as commercial success, failure of others, long-felt need, and unexpected results must be considered before a conclusion on obviousness is reached.

Patent Law > Claims & Specifications > Enablement Requirement > Proof
Patent Law > Claims & Specifications > Enablement Requirement > Standards & Tests

HN11 Enablement is a legal determination of whether a patent enables one skilled in the art to make and use the claimed invention, is not precluded even if some experimentation is necessary, although the amount of experimentation needed must not be unduly extensive, and is determined as of the filing date of the patent application. Furthermore, a patent need not teach, and preferably omits, what is well known in the art.

Patent Law > Claims & Specifications > Best Mode > Adequate Disclosure

HN12 Under 35 U.S.C.S. § 112, the specification shall set forth the best mode contemplated by the inventor of carrying out his invention. In order to find that the best mode requirement is not satisfied, it must be shown that the applicant knew of and concealed a better mode than he disclosed.

Patent Law > Claims & Specifications > Definiteness > General Overview
Patent Law > Claims & Specifications > Enablement Requirement > General Overview

HN13 Under the law pertaining to indefiniteness, if the claims, read in light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as

precise as the subject matter permits, the courts can demand no more.

COUNSEL: Douglas E. Olson, Lyon & Lyon, of Los Angeles, California, argued for Appellant. With him on brief were James W. Geriak and Bradford J. Duft.

David J. Brezner, Flehr, Hohback, Test, Albritton & Herbert, of San Francisco, California, argued for Appellee. Barry E. Britschneider and Herbert I. Cantor, of Washington, District of Columbia, of Counsel.

JUDGES: Rich, Davis, and Smith, Circuit Judges.

OPINION BY: RICH

OPINION

[*1368] RICH, Circuit Judge.

This appeal is from the August 28, 1985, decision of the United States District Court for the Northern District of California, 623 F. Supp. 1344, 227 U.S.P.Q. (BNA) 215, in favor of defendant Monoclonal Antibodies, Inc. (Monoclonal) holding that all 29 claims of plaintiff's patent No. 4,376,110 entitled "Immunometric Assays Using Monoclonal Antibodies" ('110 patent), issued to Dr. Gary S. David and Howard E. Greene and assigned to Hybritech Incorporated (Hybritech), are invalid as anticipated under 35 USC § 102(g), for obviousness under § 103, and under § 112 first [**2] and second paragraphs. We reverse and remand.

Background

Vertebrates defend themselves against invasion by microorganisms by producing antibodies, proteins which can complex with the invading microorganisms and target them for destruction or removal. In fact, any foreign molecule of sufficient size can act as a stimulus for antibody production. Such foreign molecules, or antigens, bear particular sites or epitopes that represent antibody recognition sites. B cell lymphocytes, the cells that actually produce antibodies, recognize and respond to an epitope on an antigen by reproducing or cloning themselves and then producing antibodies specific to that epitope. Even if the antigen is highly purified, the lymphocytes will produce antibodies specific to different epitopes on the antigen and so produce antibodies with different specificities. Furthermore, because the body is exposed to many different antigens, the blood of a vertebrate will contain antibodies to many different antigenic substances.

Scientists and clinicians have long employed the ability of antibodies to recognize and complex with antigens as a tool to [*1369] identify or label particular cells or molecules [**3] and to separate them from a mixture. Their source of antibodies has been primarily the serum separated from the blood of a vertebrate immunized or exposed to the antigen. Serum, however, contains a mixture of antibodies directed to numerous antigens and to any number of epitopes on a particular antigen. Because such a mixture of antibodies arises from many different clones of lymphocytes, it is called "polyclonal."

Recent technological advances have made it possible to isolate and cultivate a single clone of lymphocytes to obtain a virtually unlimited supply of antibodies specific to one particular epitope. These antibodies, known as "monoclonal antibodies" because they arise from a single clone of lymphocytes, are produced by a relatively new technology known as the hybridoma. Hybridomas are produced by fusing a particular cancer cell, the myeloma cell, with spleen cells from a mouse that has been injected or immunized with the antigen. These fusions are isolated by transferring them to a growth fluid that kills off the unfused cancer cells, the unfused spleen cells dying off by themselves. The fused hybrid spleen and myeloma cells, called hybridomas, produce antibodies to the [**4] antigen initially injected into the mouse. The growth fluid containing the hybridomas is then diluted and put into individual test tubes or wells so that there is only one hybridoma per tube or well. Each hybridoma then reproduces itself and these identical hybridomas each produce identical monoclonal antibodies having the same affinity and specificity. In this way, a virtually unlimited supply of identical antibodies is created, directed to only one epitope on an antigen rather than, as with polyclonal antibodies, to many different epitopes on many different antigens.

In addition to the specificity of antibodies to particular epitopes discussed above, antibodies also have a characteristic "sensitivity," the ability to detect and react to antigens. Sensitivity is expressed in terms of "affinity:" the greater an antibody's ability to bind with a particular antigen, the greater the antibody's affinity. The strength of that antibody-antigen bond is in part dependent upon the antibody's "affinity constant," expressed in liters per mole, for the antigen.

Immunoassays, the subject matter of the '110 patent, are diagnostic methods for determining the presence or amount of antigen in [**5] body fluids such as blood or urine

by employing the ability of an antibody to recognize and bind to an antigen. Generally, the extent to which the antibody binds to the antigen to be quantitated is an indication of the amount of antigen present in the fluid. Labelling the antibody or, in some cases, the antigen, with either a radioactive substance, I125, or an enzyme makes possible the detection of the antibody-antigen complex. In an extreme case, where the fluid sample contains a very low level of the antigen, binding might not occur unless the antibodies selected or "screened" for the procedure are highly sensitive.

In the case of a "competitive" immunoassay, a labelled antigen reagent is bound to a limited and known quantity of antibody reagent. After that reaction reaches equilibrium, the antigen to be detected is added to the mixture and competes with the labelled antigen for the limited number of antibody binding sites. The amount of labelled antigen reagent displaced, if any, in this second reaction indicates the quantity of the antigen to be detected present in the fluid sample. All of the antigen attached to the antibody will be labelled antigen if there is no antigen [**6] in the test fluid sample. The advantage of this method is that only a small amount of antibody is needed, its drawback, generally, that the system must reach equilibrium, and thus produces results slowly.

In the case of a "sandwich" assay, otherwise known as an immunometric assay, the latter being a term coined by Dr. Lawton Miles in 1971, a quantity of unlabelled antibody reagent is bound to a solid support surface such as the inside wall of a test tube containing a complex of the fluid sample [*1370] containing the antigen to be detected and a labelled *antibody* reagent. The result is an insoluble three part complex referred to as a sandwich having antibody bread and antigen filling. This figure is illustrative of the sandwich concept:

[SEE ILLUSTRATION IN ORIGINAL]

The advantage of the sandwich assay is that it is fast and simple, its drawback that enormous quantities of antibodies are needed.

Hybritech

Hybritech, started in 1978 and joined thereafter by coinventors Green and Dr. David, has, since 1979, been in the business of developing diagnostic kits employing monoclonal antibodies that detect numerous antigens and thus a broad range of conditions [**7] such as pregnancy, cancer, growth hormone deficiency, or hepatitis. Examples of antigens include influenza viruses, immunoglobulin E (IgE) which indicates allergic reaction, human chorionic gonadotropin (HCG) which indicates pregnancy, and prostatic acid phosphatase (PAP) which indicates prostate cancer, to name a few. Dr. Adams, a business-experienced scientist, joined the company in May 1980 as head of research and development. The '110 patent, application for which was filed August 4, 1980, issued March 8, 1983, with claims defining a variety of sandwich assays using monoclonal antibodies. Claim 19, apparently the broadest of the twenty-nine in the patent, is directed generally to a sandwich assay and reads (emphasis ours):

> 19. *In an immunometric assay* to determine the presence or concentration of an antigenic substance in a sample of a fluid comprising forming a ternary complex of a first labelled antibody, said antigenic substance, and a second antibody said second antibody being bound to a solid carrier insoluble in said fluid wherein the presence of the antigenic substance in the samples is determined by measuring either the amount of labelled antibody bound to [**8] the solid carrier or the amount of unreacted labelled antibody, *the improvement comprising* employing monoclonal antibodies having an affinity for the antigenic substance of at least about 10<8> liters/mole for each of said labelled antibody and said antibody bound to a sold carrier.

Claim 1, directed particularly to a reverse sandwich assay, explained infra, reads:

> 1. A process for the determination of the presence of [sic, or] concentration of an antigenic substance in a fluid comprising the steps:
>
> (a) contacting a sample of the fluid with a measured amount of a soluble first monoclonal antibody to the antigenic substance in order to form a soluble complex of the antibody and antigenic substance present in said sample, said first monoclonal antibody being labelled;
>
> (b) contacting the soluble complex with a second monoclonal antibody to the antigenic substance, said second monoclonal antibody being bound to a solid carrier, said solid carrier being [*1371] insoluble in said fluid, in order to form an insoluble complex of said first monoclonal antibody, said antigenic substance and said second monoclonal antibody bound to said solid carrier;
>
> (c) [**9] separating said solid carrier from the fluid sample and unreacted labelled antibody;
>
> (d) measuring either the amount of labelled antibody associated with the solid carrier or the amount of unreacted labelled antibody; and

(e) relating the amount of labelled antibody measured with the amount of labelled antibody measured for a control sample prepared in accordance with steps (a)-(d), said control sample being known to be free of said antigenic substance, to determine the presence of antigenic substance in said fluid sample, or relating the amount of labelled antibody measured with the amount of labelled antibody measured for samples containing known amounts of antigenic substance prepared in accordance with steps (a)-(d) to determine the concentration of antigenic substance in said fluid sample, the first and second monoclonal antibodies having an affinity for the antigenic substance of at least about 10 <8> liters/mole.

The District Court Decision

Hybritech sued Monoclonal March 2, 1984, for damages and an injunction alleging that the manufacture and sale of Monoclonal's diagnostic kits infringed the '110 patent. Trial without a jury began on August 5, 1985, and [**10] concluded August 23, 1985, thirty witnesses having been heard and over 2,000 pages of transcript generated. The district court produced the reported opinion, findings, and conclusions, which use nearly verbatim Monoclonal's *pre-trial* brief and *pre-trial proposed* findings of fact and conclusions of law, in three days, in support of the judgement now on appeal.

The district court held that the claimed subject matter of the '110 patent was neither conceived nor actually reduced to practice before May 1980, and was anticipated under § 102(g) by the actual reduction to practice of the invention by Drs. Uotila and Ruoslahti at the La Jolla Cancer Research Foundation (LJCRF) as early as November of 1979 and by the actual reduction to practice of the invention by Drs. Oi and Herzenberg (Oi/Herzenberg work) at the Stanford University Laboratory as early as July 1978, later published in December of 1979.

The district court also held the claims of the '110 patent invalid for obviousness from the Oi/Herzenberg work in view of (1) a February 1979 article by M. E. Frankel and W. Gerhard (Frankel article) which discloses high-affinity monoclonal antibodies, and apparently in view of [**11] numerous other references including; (2) the work of Nobel Prize winners G. Kohler and C. Milstein disclosing a Nobel Prize-worthy method for producing monoclonal antibodies in vitro (outside the body) published in an August 7, 1975, article; (3) U.S. Patent No. 4,244,940 issued to Jeong et al. disclosing a simultaneous polyclonal assay (Jeong), U.S. Patent No. 4,098,876 to Piasio et al. disclosing a reverse polyclonal sandwich assay (Piasio), U.S. Patent No. 4,016,143 to Schurrs et al. disclosing a forward polyclonal sandwich assay (Schurrs); (4) a July 1979 publication by A. C. Cuello et al. disclosing the use of monoclonal antibodies in competitive assays; and (5) eight articles dated between January 1979 and March 6, 1980, "predicting" that monoclonal antibodies would be used in future immunoassays. [1]

- - - - - - - - - - - - - - Footnotes - - - - - - - - - - - - - -

1 With respect to obviousness, one portion of the district court's opinion apparently relies on all of the above listed references, (1) -- (5), for the obviousness holding while a later portion entitled "CONCLUSIONS OF LAW" relies on only the Oi/Herzenberg and Frankel articles. Furthermore, the district court did not state that the LJCRF work was considered for purposes of § 103, although we recognize that § 102(g) prior art can be used for § 103.

- - - - - - - - - - - - - - End Footnotes- - - - - - - - - - - - - -

[**12] The district court also invalidated the patent on various grounds based on 35 USC § 112, first and second paragraphs, as hereinafter discussed.

[*1372] A. *The References*

1. *Kohler and Milstein's Nobel Prize-Winning Work: Producing Monoclonal Antibodies In Vitro For the First Time*

In early immunoassay work, polyclonal antibodies produced in vivo (in the body) in mice were used to bind with the antigen to be detected in the body fluid sample. Mice were immunized by injection with antigen so that the lymphocytes in their bodies produced antibodies that attacked the injected antigen. Those polyclonal antibodies were withdrawn from the animal's blood and used in immunoassays. The major problem was that when the mice's immune systems changed or the mice died, the antibodies changed or died too; supply was limited and uncertain.

As the examiner was aware, Kohler and Milstein developed a technique not only for producing antibodies in vitro, independent of a living body, thus eliminating

dependence on a particular animal, but for in vitro production of monoclonal antibodies by hybridomas, discussed in the Background section, supra.

Given that [**13] sandwich assays require enormous amounts of antibodies, companies like appellant and appellee, which utilize monoclonal antibodies for sandwich assays, would not be in business were it not for the work of Kohler and Milstein.

2. *The Work of Drs. Ruoslahti, Uotila, and Engvall at the La Jolla Cancer Research Foundation (LJCRF) in 1979 and 1980*

Dr. Ruoslahti performed mostly competitive immunoassays using polyclonal antibodies to alphafetoprotein (AFP) antigens at the City of Hope since 1970. Dr. Uotila joined him in late 1978 to perform immunoassays using monoclonal antibodies to AFP. After producing monoclonal antibodies to AFP and performing competitive radio immunoassays (RIA -- a competitive assay that uses a radioactive label) with monoclonal antibodies at the City of Hope in mid-1979, Drs. Ruoslahti, Uotila and Engvall left LJCRF.

In the fall of 1979, September or October according to Dr. Uotila, discussion and work began on using monoclonal antibodies to AFP in a sandwich assay. Dr. Uotila, the principal researcher in this particular endeavor, generated six notebooks while at the City of Hope and LJCRF. The next-to-last page of notebook four contained a note to [**14] Dr. Uotila from Dr. Ruoslahti reading:

> Sometime you should enzyme label a good monoclonal antibody so that you can set up a sandwich assay. If you use two monoclonal antibodies, you may be able to do the assay with a single incubation, since the monoclonal antibodies are likely to be directed against different determinants and not compete with one another.

Although Dr. Uotila's notebook pages were, for the most part, unsigned, undated, and uncorroborated, Dr. Ruoslahti's testimony, placed the date of this note at about October 1979 by referring to the first pages of notebook five which were dated in early November 1979. Dr. Ruoslahti testified that one curve on one graph on page 43D of notebook five showed a successful simultaneous sandwich assay using monoclonal antibodies about November 5, 1979, although no data supporting that graph could be found elsewhere in the notebook. He further testified that the affinity of the monoclonal antibodies used for that test was not calculated until 1980 but that the raw data necessary for that calculation was generated in 1979.

Dr. Uotila stated in her deposition (she did not testify at trial) that she started work on a sandwich [**15] assay using monoclonal antibodies between October 4 and the end of that month, 1979, and that she could not remember the procedure used nor was there enough information in her notebook, including page 43D, to refresh her memory. She did remember, although she continued work on this assay because the tests did not yield repeatedly good curves without which she would not publish her work, that the assay on page 43D was successful. Dr. Engvall testified about a discussion of Dr. Uotila's monoclonal antibody work with [*1373] her while at the City of Hope and about first performing a sandwich assay after arriving at LJCRF in 1979.

3. *The Work of Drs. Oi and Herzenberg at the Stanford University Laboratory in 1978 Published in December 1979*

Drs. Oi and Herzenberg used monoclonal antibodies to "map" epitopes or determine the number and location of different antibody binding sites on a known quantity of IgE antigen by attaching to it an antibody bound to a carrier and exposing that antigen to other monoclonal antibodies. The antibodies either attached to epitopes on the antigen or were blocked from doing so by the other monoclonal antibodies, depending on the location and [**16] number of epitopes; if the epitopes on the antigen were too close together and the number of antibodies too great, few antibodies would bind to the antigen. Hybritech points out that both Dr. Herzenberg and Dr. Oi testified that *their work did not involve determining the presence or quantity of antigen*, that they had no idea what the affinities of the monoclonal antibodies used were, and that those values were never calculated.

One unsigned, unwitnessed page from three large laboratory notebooks, which Hybritech argues is insufficient because it does not identify the chemical reagents or protocol used, was relied on by Monoclonal to establish actual reduction to practice of the Oi/Herzenberg work in 1978 to establish a case of § 102(g) prior invention by another. The district court agreed with Monoclonal that the Oi/Herzenberg work anticipated the claimed invention and, in addition, combined this work with the Frankel publication to hold that the claimed subject matter was obvious under § 103.

4. *The Frankel Article: Monoclonal Antibodies Having Affinities of 10 (9) liters/mole*

Frankel describes an RIA (radioimmunoassay) method for the rapid determination of affinity [**17] constants for monoclonal antibodies produced from hybridomas. The article states that the assay used is applicable only to antibodies with binding constants of about 10 <10> liters/mole and discloses the binding constants for antibodies to

several closely related strains of influenza virus.

The district court found that Frankel disclosed monoclonal antibodies having the affinity constants claimed in the '110 patent, 10 <8> to over 10 <9> liters/mole.

5. *The Cuello Article and the Jeong, Piasio, and Schurr Patents Considered by the Examiner*

Cuello, dated July 1979, states that it describes the usefulness of monoclonal antibodies in the characterization and localization of neurotransmitters such as Substance P, a peptide clearly associated with the transmission of primary sensory information in the spinal cord. The article discloses producing monoclonal antibodies from hybrid myelomas (hybridomas), their use in conventional radioimmunoassay techniques, and the benefits from doing so which flow from the ability to derive permanent cell lines capable of continuous production of highly specific antibodies.

The district court found that the examiner twice rejected all of the [**18] claims of the '110 patent based on Cuello alone or in combination with the Jeong, Piasio, and Schurr references which disclose various sandwich assays using polyclonal antibodies. The court also found that the examiner allowed the claims after they were amended to include the 10 <8> affinity limitation and after Richard Bartholomew, a Hybritech employee, submitted an affidavit alleging the advantages of using monoclonal rather than polyclonal antibodies in sandwich assays.

Apparently based on the testimony of Monoclonal's expert witness Judith Blakemore, a named inventor of the Jeong patent, manager of antibody programs at Bio-Rad Laboratories from 1975 to 1982, and currently manager of monoclonal antibody therapeutics at Cetus Corporation, a Hybritech competitor in immunoassay diagnostics, the district court stated that the "reasons for allowance were not well-founded because (1) the alleged advantages were [*1374] expected as naturally flowing from the well-known natural characteristics of monoclonal antibodies . . .; (2) . . . were not significant . . .; or (3) were at best minor," although they were "argued to the examiner as if they were" important. These were Monoclonal's [**19] words from its pretrial submission adopted by the court.

6. *The References That "Predicted" the Use of Monoclonal Antibodies in Immunoassays*

The district court stated, again in Monoclonal's words, that "it is of the utmost importance" that the advantages of monoclonal antibodies were "predicted by a number of authorities," eight to be exact, not important enough to list here, after the Kohler and Milstein discovery and after monoclonal antibodies became available.

B. *The Claimed Subject Matter of the '110 Patent*

Hybritech argues that the district court's determination that there is no credible evidence of conception or reduction to practice of the '110 invention before May 1980 is error because Dr. David's laboratory notebooks, Nos. 21 and 24, clearly show successful sandwich assays using monoclonal antibodies in August, September, and October of 1979. At the least, argues Hybritech, the invention was conceived in January of 1979, long before Drs. Ruoslahti, Engvall, and Uotila began work on a sandwich assay using monoclonal antibodies, and diligence was thereafter exercised until constructive reduction to practice occurred by the filing of the '110 patent application [**20] on August 4, 1980.

Dr. David and Greene testified that pages 2118 to 2122 of Dr. David's notebook, dated January 4, 1979, and witnessed January 30, 1979, disclose the generic conception of the invention in the context of the physical support structure used to carry out a sandwich assay, and Dr. David testified on redirect that (1) Page 1128 of notebook 21, dated May 27, 1979, recorded an early attempt at a sandwich assay that failed, (2) on August 3, 1979, as recorded at page 1166, a sandwich assay using monoclonal antibody 068 attached to a solid carrier, a radio-labelled 068 antibody, and a hepatitis antigen from an Abbott Labs polyclonal competitive assay kit was successfully performed, and (3) a sandwich assay using a bound 259 antibody, a radio-labelled 068 antibody, and a hepatitis antigen was successfully performed on September 21, 1979. Hybritech also urges that work in October 1979 directed to determining whether certain monoclonal antibodies were recognizing the same or different determinants, was a reduction to practice.

Monoclonal points out that these notebook pages do not expressly state that monoclonal antibodies of 10 <8> liters/mole affinity were used in a sandwich [**21] assay and that the May, August, and September notebook entries were not witnessed until about the time Dr. Adams, experienced in patent matters, joined Hybritech and advised its researchers on properly recording laboratory work. They therefore claim that actual reduction to practice was not shown before May 1980.

OPINION

I. *Review Under Rule 52(a) Fed. R. Civ. P.*

Rule 52(a) HN1 "ensures care in the preparation of an opinion . . . and provides appellate courts with the benefit of the District Court's insights into a case," *Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309, 318, 227 U.S.P.Q. (BNA) 766, 772 (Fed. Cir. 1985) (Harvey, Senior District Judge, concurring) by requiring a district court to "find the facts specially and state separately its conclusions of law thereon." With the exception of the first eight paragraphs, the first half of the district court's opinion here is Monoclonal's *pretrial* brief and the last three pages of the opinion are Monoclonal's *pretrial* findings of fact and conclusions of law. The district court adopted the above documents [**22] virtually verbatim, with the exception of portions of each concerning inequitable conduct and noninfringement, apparently without inviting a response from Hybritech, resulting in a repetitious (as the district court admitted in [*1375] the opinion), sometimes internally inconsistent, and hard to follow opinion that presents us with a difficult task in gleaning the basis for many of the conclusions. For some of the findings, submitted before trial, no supporting evidence was introduced at trial.

The Supreme Court, in *Anderson v. City of Bessemer City, N.C.*, 470 U.S. 564, 105 S. Ct. 1504, 84 L. Ed. 2d 518 (1985), strongly criticized the practice of "verbatim adoption of findings of fact prepared by prevailing parties, particularly when those findings have taken the form of conclusory statements unsupported by citation to the record." *Anderson*, supra at 1511. This court also has cautioned against the adoption of findings, especially when proposed by a party before trial, as here, and stated that the likelihood of clear error in those findings increases in such a situation. *Lindemann Maschinenfabrik v. American Hoist and Derrick*, 730 F.2d 1452, 221 U.S.P.Q. (BNA) 481, 485 (Fed. Cir. 1984). [**23] Notwithstanding our misgivings about whether the findings in this case, prepared before any evidence was introduced, satisfy the objectives of Rule 52(a) -- a carefully prepared opinion providing the reviewing court with the benefit of the district court's *reasoned insights* into the case -- those HN2 findings are the district court's and may be reversed only if clearly erroneous. *See Anderson*, supra, at 1511; *Lindemann*, 730 F.2d at 1457, 221 U.S.P.Q. at 485.

"A finding is clearly erroneous when, although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." *United States v. United States Gypsum Co.*, 333 U.S. 364, 395, 92 L. Ed. 746, 68 S. Ct. 525 (1948). "This standard plainly does not entitle a reviewing court to reverse the finding of the trier of fact simply because it is convinced that it would have decided the case differently." *Anderson*, supra, at 1511. In other words, "if the district court's account of the evidence is plausible in light [**24] of the record viewed in its entirety" or "where there are two permissible views of the evidence," the factfinder cannot be clearly erroneous. *Anderson*, supra, at 1511 (quoting *United States v. Yellow Cab Co.*, 338 U.S. 338, 70 S. Ct. 177, 94 L. Ed. 150 (1949)). This is so, stated the Court in dictum, *see Anderson*, supra, at 1516 (Blackmun, J., concurring), even when the district court's findings rest on physical or documentary evidence or inferences from other facts and not on credibility determinations. *See also* Rule 52(a) Fed. R. Civ. P. (as amended Aug. 1, 1985). If the latter are involved, "Rule 52 demands even greater deference to the trial court's findings" but a trial judge may not "insulate his findings from review by denominating them credibility determinations"; HN3 if documents or objective evidence contradict the witness's story, clear error may be found even in a finding purportedly based on a credibility determination. *Anderson*, supra, at 1512-13. We proceed in light of all these principles.

II. *Presumption of Validity*

[**25] HN4 Under 35 USC § 282, a patent is presumed valid, and the one attacking validity has the burden of proving invalidity by clear and convincing evidence. *See, e.g., American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360, 220 U.S.P.Q. (BNA) 763, 770 (Fed.Cir. 1984). Notwithstanding that the introduction of prior art not before the examiner may facilitate the challenger's meeting the burden of proof on invalidity, the presumption remains intact and on the challenger throughout the litigation, and the clear and convincing standard does not change. *See, e.g., Jervis B. Webb Co. v. Southern Systems, Inc.*, 742 F.2d 1388, 1392 & n.4, 222 U.S.P.Q. (BNA) 943, 945 & n.4 (Fed. Cir. 1984). The only indication that the district court recognized the presumption of validity and its proper application was its statement that "the key issue in this case is whether the defendant has overcome the presumption of nonobviousness." That statement, however, speaks only part of the truth; the presumption of validity goes to validity of the patent in relation to the patent statute *as a* [**26] *whole*, not just to nonobviousness under section 103.

[*1376] III. *Prior Invention of Another, 35 USC § 102(g)*

Section 102(g) HN5 states that a person shall be entitled to a patent unless "before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it." Section 102(g) "relates to prior inventorship by another in this country" and "retains the rules governing the determination of priority of invention. . . ." *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1444, 223 U.S.P.Q. (BNA) 603, 606 (Fed. Cir. 1984) (quoting P.J. Federico, *Commentary on the New Patent Act*, 35 USCA page 1, at 19 (1954)). Section 102(g) says: HN6 "In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other."

[**27] HN7 Reduction to practice, and conception as well, is a legal determination subject to review free of the clearly erroneous standard. Barmag Barmer Maschinenfabrik AG v. Murata Machinery, Ltd., 731 F.2d 831, 837, 221 U.S.P.Q. (BNA) 561, 565-66 (Fed. Cir. 1984); D.L. Auld Co. v. Chroma Graphics Corp., 714 F.2d 1144, 1151, 219 U.S.P.Q. (BNA) 13, 18 (Fed. Cir. 1983). Findings of fact supporting that legal conclusion are, of course, reviewed under the clearly erroneous standard.

HN8 Conception is the "formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." 1 *Robinson On Patents* 532 (1890); Coleman v. Dines, 754 F.2d 353, 359, 224 U.S.P.Q. (BNA) 857, 862 (Fed. Cir. 1985). Actual reduction to practice requires that the claimed invention work for its intended purpose, *see, e.g.*, Great Northern Corp. v. Davis Core & Pad Co., 782 F.2d 159, 165, 228 U.S.P.Q. (BNA) 356, 358, (Fed. [**28] Cir. 1986), and, as has long been the law, constructive reduction to practice occurs when a patent application on the claimed invention is filed. Weil v. Fritz, 572 F.2d 856, 865 n.16, 196 U.S.P.Q. (BNA) 600, 608 n.16 (CCPA 1978) (citing with approval Automatic Weighing Machine Co. v. Pneumatic Scale Corp., 166 F. 288 (1st Cir. 1909)).

After a review of the record in its entirety, including the numerous corroborating Hybritech laboratory notebooks, internal documents, and pertinent testimony, we hold clearly erroneous the district court's finding that there is no clear or corroborated evidence "with regard to when before May 1980, the idea of actually using monoclonals in sandwich assays" was conceived or, more properly, or when the *claimed invention* was conceived, and therefore reverse the court's holding, as a matter of law, that Hybritech's inventors did not conceive the claimed invention before May 1980.

Hybritech's claim of conception, generally, is evidenced by the sometimes sparsely documented work of a start-up company whose first small advances evolved into the myriad activities of a mature company with efforts directed toward developing [**29] the claimed invention by first employing the Kohler and Milstein technology to produce the necessary monoclonal antibodies and using those antibodies in diagnostic sandwich assay kits. There is no doubt that exploiting monoclonal antibodies for use in sandwich assays was one of the major objectives of Hybritech. In a letter to Pharmacia Fine Chemicals dated April 26, 1979, Greene, in responding to Pharmacia's interest in Hybritech's products, outlined the latter's "efforts to bring the exciting new hybridoma technology into routine medical use" and its exploration of "several intriguing concepts for which monoclonals may open up new immunodiagnostic techniques heretofore infeasible with animal serums." Although company minutes in early 1979 contain little about the claimed subject matter and some of the discussions thereon, such as Greene's and Dr. Adams' conversation about monoclonal sandwich assays when the former was trying to woo Dr. Adams to join Hybritech were unrecorded, the Hybritech laboratory notebooks and the [*1377] nature of Hybritech's research program fully corroborate the testimonial evidence of conception and thus clearly support our holding that Hybritech conceived [**30] the claimed invention before LJCRF.

Dr. David's January 1979 notebook describes, in detail, as explained by Greene and Dr. David at trial, a nylon apparatus that undoubtedly could be used for performing a sandwich assay using monoclonal antibodies, although Dr. David testified on cross-examination that at that time Hybritech had not yet developed any monoclonal antibodies, including attaching one of the reagents to a solid carrier ring, contacting that ring with a fluid sample in a microtiter plate well, adding a labelled reagent to the well after rinsing, and then "counting" or measuring the amount of either the labelled or unlabelled reagent after a prescribed time and second rinsing. The notebook then describes the procedure for detecting an antibody "(a-x)" to an antigen "(x)" complete with diagrams and text, both illuminated by Dr. David at trial. The notebook further states, "Alternatively, if one wished to quantitate an antigen, y, the identical procedure would be followed, except that reagents would be reversed, i.e. the reaction would be:" and there follows a clear illustration of an antibody attached to a solid carrier reacting with an antigen to form a complex, and that [**31] complex reacting with a second labelled antibody. The notebook was signed by Dr. David on January 4, 1979, and witnessed and signed on January 30 of the same year by Dr. Curry, the first cell biologist hired at Hybritech to set up the hybridoma production program.

Dr. David testified on direct that monoclonal antibodies were developed in the following months: antigens were purchased from outside sources and purified before being injected into mice; the spleen cells from those mice were fused with myelomas; and the resultant hybridomas were separated into well plates for development, and a radioimmunoassay procedure was carried out to determine the affinity of the antibodies.

The May 1979 failed sandwich assay, witnessed in May 1980, corroborates Dr. David's testimony that a polyclonal antibody bound to be a solid carrier and a labelled monoclonal antibody were used in a sandwich assay with an antigen from Abbott Labs' Ausria polyclonal diagnostic kit for hepatitis. No binding was detected.

Dr. David testified about the experiment documented in the August 1979 notebook, a sandwich assay with a hepatitis antigen from an Abbott Labs Ausria kit with two Hybritech 068 monoclonal [**32] antibodies, one attached to a solid carrier bead and the other labelled; the purpose of the experiment was to quantitate the antigen. The notebook corroborates Dr. David's testimony that the test was positive and lists the counts per minute of the labelled antibody. Defendant Monoclonal's expert Ciotti testified about this experiment:

> Also, of course, it is limited to -- it is limited to hepatitis antigen. And without a generic conception, it would just be merely a -- if it did work for its intended purpose -- which I would assume for purposes of discussion -- *it would be a reduction to practice of one embodiment*. And without a corresponding generic conception, I don't think it would be held to be the making of the invention in terms of, for instance, in claim 19. [Emphasis ours.]

Dr. David further testified that the September 21, 1979, record in David's notebook, witnessed months later, shows a reverse sandwich assay using a bound 259 monoclonal antibody and a labelled 068 monoclonal antibody with a hepatitis antigen with results confirmed by a dose response curve. [2] Hybritech further alleges that a laboratory notebook page dated October 1979 is a reduction [**33] to practice of the [*1378] claimed invention but fails to cite any related testimony or other evidence in support thereof.

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2 A dose response curve is antigen concentration plotted against the signal produced by labelled antibody in an immunoassay. The signal increases with increasing antigen concentration in a successful assay but at some point decreases when the antigen concentration becomes too high.

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Finally, the record shows that the claimed affinity limitation "of at least about 10 <8> liters/mole" was determined and appreciated during the course of the development of the claimed subject matter. Dr. David and Dr. Adams separately testified that the screening procedures used by Hybritech ensured that only monoclonal antibodies having at least 10 <8> liters/mole affinity would be used in assays. An October 1979 internal memorandum from Greene to the staff states, "To improve comparisons we will express all affinities to the base ten to the eighth which represents the lower end of the usable range."

[**34] We are left with the definite and firm conviction that a mistake has been committed because the district court's account of the evidence that "there was no credible evidence of conception before May 1980" is insupportable. There is such evidence. The laboratory notebooks, alone, are enough to show clear error in the findings that underlie the holding that the invention was not conceived before May 1980. That some of the notebooks were not witnessed until a few months to one year after their writing does not make them incredible or necessarily of little corroborative value. Admittedly, Hybritech was a young, growing company in 1979 that failed to have witnesses sign the inventors' notebooks contemporaneously with their writing. Under a reasoned analysis and evaluation of all pertinent evidence, however, we cannot ignore that Hybritech, within a reasonable time thereafter, prudently had researchers other than those who performed the particular experiments witness the notebooks in response to Tom Adams' advice. The notebooks clearly show facts underlying and contemporaneous with conception of the claimed invention and in conjunction with the testimony of Dr. David and Greene, [**35] and others, are altogether legally adequate documentary evidence, under the law pertaining to conception, of the formation in the minds of the inventors of a definite and permanent idea of the complete and operative invention as it was thereafter applied in practice. We thus are not moved by Monoclonal's argument that the findings of fact underlying conception are based on credibility determinations and are more sacrosanct than usual. *See* Anderson, supra, at 1512-13.

1. *LJCRF Is Not Prior Art*

Hybritech laboratory notebooks and the uncontradicted testimony of Dr. David and Mr. Greene show that development of the claimed invention proceeded diligently through the rest of 1979 and 1980, there being absolutely no evidence of record nor even argument by Monoclonal that Hybritech was not diligent in its efforts to reduce to practice the claimed invention during the period January 1979 to the '110 application filing date of August 4, 1980. We therefore hold as a matter of law that Hybritech's conception, which was before LJCRF conceived the claimed invention, coupled by diligence to its constructive reduction to practice by the filing of the '110 application, entitle Hybritech [**36] to priority over LJCRF. *See* 35 USC § 102(g). The work of LJCRF is therefore not prior art.

We also note that there is inadequate factual basis for the district court's holding that LJCRF reduced the claimed invention to practice as early as November 1979 because the only evidence that corroborates the testimony of Ruoslahti, Uotila, and Engvall is the note from Ruoslahti to Uotila, see section A, 2, supra, which indisputably is not the claimed invention, and the *one* curve from *one* graph from only one page, 43D, of the six Uotila notebooks. After a reasoned examination, analysis, and evaluation of this pertinent evidence we conclude that it falls far short of showing the "formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice," *see* Coleman, 754 F.2d at 359, 224 U.S.P.Q. at 862, and therefore is legally inadequate to support even a holding of *conception* of [*1379] the claimed invention by LJCRF personnel in 1979.

(1) It is undisputed that page 43D was not signed, witnessed, or dated; (2) the deposition testimony of [**37] Uotila was that she could not remember the procedure used to

arrive at the dose-response curve on page 43D and there was not enough information in her notebook to refresh her memory; (3) the testimony of Ruoslahti was that he could find *no* data in the notebook supporting that graph, none of the *later* graphs shown there represented successful assays and that "especially after this was done, we ran into more severe problems. And it took us a while to do away with the problems;" (4) Ruoslahti also testified that they never determined, in 1979, the affinities of the monoclonal antibodies they used, and that the title of page 43D had been altered at some point -- the word "inhibition" had been crossed out and "sandwich" written in; and (5) the testimony of Engvall was that there was nothing about the shape of those curves which indicates that they were sandwich assays. We also note, as evidence bearing upon the credibility of Ruoslahti's testimony (that LJCRF actually reduced the claimed invention to practice in 1979), that when LJCRF attempted to provoke an interference in the PTO with Hybritech based on the U.S. filing of an application that was the counterpart to a Swedish application [**38] disclosing similar subject matter, LJCRF could not demonstrate even a *prima facie* reduction to practice prior to Hybritech's August 4, 1980, filing date. During that proceeding, the earliest dates Ruoslahti set down on paper to support conception and reduction to practice were in 1980.

2. *The Work of Oi/Herzenberg Is Not the Claimed Invention*

HN9 It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention, and that such a determination is one of fact. *See, e.g.,* Lindemann, supra, 730 F.2d at 1458, 221 U.S.P.Q. at 485; *Great Northern Corp. v. Davis Core & Pad Co.*, 782 F.2d 159, 165, 228 U.S.P.Q. (BNA) 356, 358 (Fed. Cir. 1986). Section 102(g) upon which the district court relied is one type of "anticipation," i.e., prior invention by another of the same invention. Drs. Oi and Herzenberg testified that their work did not involve detecting the presence of or quantitating antigen but a determination of the number and location of epitopes on a *known* quantity of antigen. Although this work did [**39] involve a sandwich assay to the extent that an antigen was sandwiched between two monoclonal antibodies, it is clear that the similarity between that work and the claimed invention goes no further. Furthermore, both doctors testified that they did not know the affinities of the antibodies that were used in their mapping work and in fact never calculated them. Ciotti, Monoclonal's expert, testified that the 10<8> affinity limitation cannot be found anywhere in the Oi/Herzenberg work. Again we are left with a definite and firm conviction that a mistake was made because that work does not meet every element of the claimed invention. The district court's finding to the contrary is clearly erroneous.

We note that the district court, in also holding the patent invalid under § 103, next considered, combined the Oi/Herzenberg work with the Frankel reference, one justifiable inference therefrom being that the court recognized that Frankel discloses a claim *element* that Oi/Herzenberg does not, namely, at least about 10<8> liters/mole affinity.

IV. *Obviousness, 35 USC § 103*

[**40] HN10 A section 103 obviousness determination -- whether the claimed invention *would have been* (not "would be" as the court repeatedly stated because Monoclonal's pretrial papers used that improper language) obvious at the time the invention was made is reviewed free of the clearly erroneous standard although the underlying factual inquiries -- scope and content of the prior art, level of ordinary skill in the art, [3] and differences between the prior art [*1380] and the claimed invention -- integral parts of the subjective determination involved in § 103, are reviewed under that standard. Objective evidence such as commercial success, failure of others, long-felt need, and unexpected results must be considered *before* a conclusion on obviousness is reached and is not merely "icing on the cake," as the district court stated at trial. *See* Lindemann, supra, 730 F.2d at 1461, 221 U.S.P.Q. at 488; *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 U.S.P.Q. (BNA) 871 (Fed. Cir. 1983); *Kansas Jack, Inc. v. Kuhn*, 719 F.2d 1144, 219 U.S.P.Q. (BNA) 857 (Fed. Cir. 1983); *W.L. Gore & Associates v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. (BNA) 303, 314 (Fed. Cir. 1983). [**41]

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3 Although the district court failed expressly to find the level of ordinary skill in the art at the time the invention was made, it did make reference to "people working in immunology aware of the Kohler and Milstein discovery" which we deem an accurate finding for the purposes of that portion of the *Graham* factual inquiries.

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1. *The Eight Articles "Predicting" Widespread Use of Monoclonal Antibodies*

Before discussing the more pertinent references in this case -- the Oi/Herzenberg and Frankel works -- we cull the other prior art references relied on by the trial court.

First, the latest four of the eight articles that the court stated were of the "utmost importance" because they "predicted" that the breakthrough in production of monoclonal

antibodies by Kohler and Milstein would lead to widespread use of monoclonal antibodies in immunoassays are neither 102(a)/103 nor 102(b)/103 prior art because they are dated between late 1979 and March 6, 1980, well after the date of conception and within one [**42] year of the filing date of the '110 patent.

The earliest four of the eight articles, on the other hand, although clearly prior art, discuss *production* of monoclonal antibodies -- admittedly old after Kohler and Milstein showed how to produce them -- but none discloses sandwich assays. At *most*, these articles are invitations to try monoclonal antibodies in immunoassays but do not suggest how that end might be accomplished. To the extent the district court relied upon these references to establish that it would have been *obvious to try* monoclonal antibodies of 10<8> liters/mole affinity in a sandwich immunoassay that detects the presence of or quantitates antigen, the court was in error. *See Jones v. Hardy*, 727 F.2d 1524, 1530, 220 U.S.P.Q. (BNA) 1021, 1026 (Fed.Cir. 1984) ("Obvious to try" is improper consideration in adjudicating obviousness issue). [4]

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4 Finding 10, which states that the invention was contemporaneously developed and disclosed in at least five publications and patent applications not listed above *and dated well after the filing date of the '110 patent but before its issuance* is irrelevant for purposes of the hypothesis based on the three factual inquiries required by § 103 as interpreted by *Graham v. John Deere*, 383 U.S. 1, 148 U.S.P.Q. (BNA) 459, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966) because obviousness must be determined as of the time the invention was made. Additionally, they are of little probative value in this case because they are dated December 1981 at the earliest, more than a year after the August 4, 1980, filing date here and roughly two years after conception occurred. Furthermore, simultaneous development may or may not be indicative of obviousness, the latter being the case here for the above reasons and because the other evidence of nonobviousness is adequate, such occurrences having been provided for in 35 USC § 135. *Lindemann*, supra, 730 F.2d at 1460-61, 221 U.S.P.Q. at 487; *Environmental Designs, Ltd. v. Union Oil Co. of California*, 713 F.2d 693, 698 n.7, 218 U.S.P.Q. (BNA) 865, 869 n.7 (Fed. Cir. 1983).

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[**43] 2. *The Kohler and Milstein Work, the Cuello Article and the Jeong, Piasio, and Schurr Patents Considered by the Examiner*

The district court's finding that Kohler and Milstein developed a method for producing monoclonal antibodies in vitro is correct, but that finding proves no more; although it made possible all later work in that it paved the way for a supply of monoclonal antibodies, it indisputably does not suggest using monoclonal antibodies in a sandwich assay in accordance with the invention claimed in the '110 patent.

The Cuello reference discloses monoclonal antibodies but not in a sandwich assay. The competitive assay in Cuello, moreover, [*1381] uses only one monoclonal antibody and thus in no way suggests the claimed invention wherein a ternary complex of two monoclonal antibodies and an antigen form a sandwich. Furthermore, the court did not explain how this art, by itself or in combination with any of the other art, suggests the claimed subject matter and thus why that combination would have been obvious. We are of the opinion that it does not.

The district court correctly found that the use of polyclonal antibodies in sandwich assays was well known. [**44] The Jeong patent discloses the use of polyclonal antibodies in a simultaneous sandwich assay, with no suggestion that monoclonal antibodies be so used. It is prior art by virtue of § 102(e), application for the patent having been filed September 5, 1978, its effective date as a reference. The Piasio patent, disclosing a reverse sandwich assay using polyclonal antibodies, and Schurrs, disclosing a forward sandwich assay using the same, both § 102(a) prior art, are likewise devoid of any suggestion that monoclonal antibodies can be used in a similar fashion.

3. *The Oi/Herzenberg Work and the Frankel Article*

Clearly, the most pertinent items of prior art not cited by the examiner are the Oi/Herzenberg work, as described in section A, 3, supra, and the Frankel article. As stated in the discussion of Prior Invention of Another (section III, 2, supra), the Oi/Herzenberg work involved mapping epitopes on a known quantity of antigen. It was not concerned with and does not disclose using monoclonal antibodies of at least 10<8> liters/mole affinity. Oi and Herzenberg testified that they did not know the affinity of the antibodies used, and Ciotti testified that nowhere in that [**45] work is there mention of monoclonal antibody affinity of at least 10<8> liters/mole. On this basis, we conclude that the Oi/Herzenberg work is qualitatively different than the claimed invention; the former is directed to mapping epitopes on a known quantity of antigen and the latter to determine the "presence or concentration of an antigenic substance in a sample of fluid . . . ." We disagree with Monoclonal that these are "essentially the same thing." Furthermore, it is perfectly clear that this work in no way suggests using monoclonal antibodies of the affinity claimed in the '110 patent. It is because of these differences between the Oi/Herzenberg work and the claimed invention that the fact that an antigen was sandwiched between two monoclonal antibodies in the course of Oi's and Herzenberg's work is not sufficient basis to conclude that the claimed invention would have been obvious at the time it was made to a person of ordinary skill in the art.

Likewise, a conclusion that the invention would have been obvious cannot properly be reached when the Oi/Herzenberg work is considered in view of the Frankel article. Frankel teaches a method for rapid determination of affinity constants [**46] for monoclonal antibodies, some of which clearly have affinities of the order defined by the claims, but does not in any way suggest using two of those antibodies in a sandwich to assay an antigen by forming a ternary complex of labelled antibody, the antigenic substance, and a bound antibody wherein the presence of the antigenic substance is determined by measuring either the amount of labelled antibody bound to a solid carrier or the amount of unreacted labelled antibody. The mere existence of prior art disclosing how to measure the affinity of high affinity monoclonal antibodies is insufficient to support a holding of obviousness. Hybritech's claims define a *process* that *employs* monoclonal antibodies, and does not merely claim antibodies of high affinity. In view of the fact that the Oi/Herzenberg work is not directed to an assay as claimed and does not disclose antibodies of at least 10<8> liters/mole affinity, and further that Frankel fails to suggest using such antibodies in a sandwich assay, the Frankel article does not compensate for the substantial difference between the Oi/Herzenberg work and the claimed subject matter, and therefore those references in combination [**47] cannot support a holding of obviousness.

[*1382] 4. *Objective Evidence of Nonobviousness*

In one part of its opinion the court found that "the commercial success of the kits *may* well be attributed to the business expertise and acumen of the plaintiff's personnel, together with its capital base and marketing abilities" (emphasis ours) and later that "where commercial success is based on the sudden availability of starting materials, in this instance the availability of monoclonal antibodies as a result of the Kohler and Milstein discovery, business acumen, marketing ability, and capital sources, no causal relationship is proven." (Citation omitted.)

i. *Commercial Success: Hybritech's Diagnostic Kits Grabbed a Substantial Market Share*

The undisputed evidence is that Hybritech's diagnostic kits had a substantial market impact. The first diagnostic kit sales occurring in mid-1981, sales increased seven million dollars in just over one year, from $6.9 million in 1983 to an estimated $14.5 million in 1984; sales in 1980 were nonexistent. Competing with products from industry giants such as Abbott Labs, Hoffman LaRoche, Becton-Dickinson, and Baxter-Travenol, Hybritech's [**48] HCG kit became the market leader with roughly twenty-five percent of the market at the expense of market shares of the other companies. Its PAP kit ranks second only to a product sold by Dupont's New England Nuclear, surpassing products from Baxter-Travenol, Abbott, and others. Hybritech's other kits, indisputably embodying the invention claimed in the '110 patent, obtained similar substantial market positions.

Although the district court did not provide its insights into why commercial success was due to business acumen and not to the merits of the claimed invention, Monoclonal urges in support that it was due to Hybritech's spending disproportionate sums on marketing, 25-30% of income. The undisputed evidence was that expenditures of *mature* companies in this field are between 17 and 32%. Furthermore, the record shows that advertising makes those in the industry -- hospitals, doctors, and clinical laboratories -- aware of the diagnostic kits but does not make these potential users buy them; the products have to work, and there is no evidence that that is not the case here or that the success was not due to the merits of the claimed sandwich assays -- clearly contrary to [**49] the district court's finding.

The trial court's finding that the "sudden availability of monoclonals" was the reason for the commercial success of Hybritech's diagnostic kits (Finding 11) is unsupported by the record and clearly erroneous. Monoclonal admits that monoclonal antibodies were available in the United States in *1978*, and the evidence clearly reflects that. Thus, at least *three years* passed between the time monoclonal antibodies were available in adequate supply and the time Hybritech began selling its kits. Especially in the fast-moving biotechnology field, as the evidence shows, that is anything but sudden availability.

ii. *Unexpected Advantages*

Hybritech points to the testimony of three witnesses skilled in the diagnostic field who state that, based on tests done in their laboratories as a result of real-world comparisons in the normal course of research, the diagnostic kits that embody the '110 invention unexpectedly solved long-standing problems. Dr. Hussa, the head of a large referral laboratory and a world-wide consultant, testified that until Hybritech introduced its kits, he and others were very skeptical and had almost exclusively used competitive [**50] assays with a radioactive tracer (RIAs). [5] In relation to an [*1383] HCG Hybritech kit, he testified that he had first thought that the Hybritech HCG kit would not give accurate results for low antigen concentrations because that condition is indicated in the Hybritech kit by a low radioactivity reading, a reading difficult to differentiate from control samples containing no antigen. He also stated that in the past, RIA kits falsely detected HCG in nonpregnant women, a condition which would indicate cancer and surgery. He stated that when he employed the Hybritech HCG kit in such instances it demonstrated, correctly and absent any difficulty interpreting the data, that no HCG was present.

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5 Monoclonal's expert Blakemore testified that of 425 assays on the market in 1979 less than 1% were sandwich assays. Today, sandwich assays constitute the majority of all assays sold.

The record also shows that Blakemore, who testified extensively for Monoclonal that the claimed invention would have been obvious, never used monoclonal antibodies in sandwich assays at Cetus before 1980. Additionally, she did not even mention them in the Jeong patent, of which she was a coinventor, which issued January 13, 1981, long after the beginning of Hybritech's work in this area in 1979.

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[**51] Dr. Blethen, an M.D. holding a Ph.D. in biochemistry, testified that she did not think that the Hybritech HGH kit, for detecting growth hormone in children, would offer any advantage, but she determined that it detected HGH deficiencies in children where conventional RIAs failed to do so. She also stated that the kit does not give false positive readings as do conventional RIA kits, an opinion shared by Dr. Hussa. A third witness, Dr. Herschman, who holds a master's degree in chemistry, testified that he spent years working on the development of an assay that would determine the presence of TSH (thyroid stimulating hormone) with greater sensitivity. He succeeded but discovered that the Hybritech TSH kit had the same sensitivity, the test being performed in four hours rather than the three days his kit required.

Having considered the evidence of nonobviousness required by § 103 and *Graham*, supra, we hold, as a matter of law, that the claimed subject matter of the '110 patent would not have been obvious to one of ordinary skill in the art at the time the invention was made and therefore reverse the court's judgment to the contrary. The large number of references, [**52] as a whole, relied upon by the district court to show obviousness, about twenty in number, skirt all around but do not as a whole suggest the claimed invention, which they must, to overcome the presumed validity, *Lindemann*, 730 F.2d at 1462, 221 U.S.P.Q. at 488, *as a whole*. See 35 USC § 103; *Jones v. Hardy*, 727 F.2d 1524, 1529, 220 U.S.P.Q. (BNA) 1021, 1024 (Fed. Cir. 1984). Focusing on the obviousness of substitutions and differences instead of on the invention as a whole, as the district court did in frequently describing the claimed invention as the mere substitution of monoclonal for polyclonal antibodies in a sandwich assay, was a legally improper way to simplify the difficult determination of obviousness. *See generally* *Hodosh v. Block Drug Co.*, 786 F.2d 1136, 229 U.S.P.Q. (BNA) 182 (Fed. Cir. 1986). [6]

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6 It bears repeating that it is crucial that counsel set forth the law accurately. More particularly, it is the duty of counsel to impart to the judge that the obviousness question properly is whether the *claimed* invention *as a whole would have been* obvious to one of *ordinary* skill in the art *at the time the invention was made*, and that the district court must *expressly* make the three factual determinations required by *Graham* and consider objective evidence of obviousness *before* the legal conclusion of obviousness vel non is made. Submitting to the court language like "any differences . . . would have been obvious," as was done here, violates the axiom that the question is not whether the differences would have been obvious but the claimed invention *as a whole*. Furthermore, arguing that "it would be obvious" rather than that it would *have been* obvious shifts the court's focus to the wrong period of time, namely to a time long after the wrong period of time, namely to a time long after the invention was made, in which, more likely than not, the prior art and the level of ordinary skill in the art are more advanced. *See* 35 USC § 103.

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[**53] With respect to the objective indicia of nonobviousness, while there is evidence that marketing and financing played a role in the success of Hybritech's kits, as they do with any product, it is clear to us on the entire record that the commercial success here was due to the merits of the claimed invention. It cannot be argued on this record that Hybritech's success would have been as great and as prolonged as admittedly it has been if that success were not due to the merits of the invention. The evidence is that these kits compete successfully with numerous others for the trust of persons who have to make fast, accurate, and safe diagnoses. This is not the kind of [*1384] merchandise that can be sold by advertising hyperbole.

V. *Enablement, Best Mode, and Definiteness Under § 112*

The section 112 defense appears to have been an afterthought of both Monoclonal, who briefly but unsuccessfully attempts to defend this utterly baseless determination, and of the district court which adopted the defense from Monoclonal's pretrial papers apparently without knowledge of the applicable law, to highlight, as it stated at trial, that it was part of its job to see that "whoever [**54] wins wins all the way or whoever loses loses all the way." Taken as a whole, the court's comments on § 112 -- split into two parts, one from Monoclonal's pretrial brief and the other from the adopted pretrial findings and conclusions -- are internally inconsistent. The opinion states that the patent fails to disclose how (1) to make monoclonal antibodies; (2) to screen for proper monoclonal antibodies; and (3) to measure monoclonal antibody affinity and

therefore the specification is nonenabling and does not satisfy the best mode requirement, and the claims are indefinite. We discuss each of these in turn.

1. *Enablement*

HN11 Enablement is a legal determination of whether a patent enables one skilled in the art to make and use the claimed invention, Raytheon Co. v. Roper Corp., 724 F.2d 951, 960, 220 U.S.P.Q. (BNA) 592, 599 (Fed. Cir. 1983), is not precluded even if some experimentation is necessary, although the amount of experimentation needed must not be unduly extensive, Atlas Powder Co. v. E.I. Du Pont De Nemours & Co., 750 F.2d 1569, 1576, 224 U.S.P.Q. (BNA) 409, 413 (Fed. Cir. 1984), [**55] and is determined as of the filing date of the patent application, which was August 4, 1980. *See* W. L. Gore and Associates v. Garlock, Inc., 721 F.2d 1540, 1556, 220 U.S.P.Q. (BNA) 303, 315 (Fed. Cir. 1983). Furthermore, a patent need not teach, and preferably omits, what is well known in the art. Lindemann, 730 F.2d at 1463, 221 U.S.P.Q. at 489.

The record fully supports the '110 patent's statement that

> The monoclonal antibodies used for the present invention are obtained by the [hybridoma] process discussed by Milstein and Kohler. . . . The details of this process are well known and not repeated here.

The district court itself stated that the "method for producing monoclonal antibodies in vitro was well known prior to the alleged invention of the '110 patent," and used the "sudden availability of monoclonal antibodies" produced by the Kohler and Milstein discovery to support, albeit erroneously, its finding of a lack of nexus between the merits of the claimed invention and its commercial success. The court then about-faced and held the '110 patent deficient because it fails to teach how to make monoclonal antibodies.

[**56] With respect to screening, the only permissible view of the evidence is that screening methods used to identify the necessary characteristics, including affinity, of the monoclonal antibodies used in the invention were known in the art and that the '110 patent contemplated one of those. At trial, Monoclonal's counsel stated "it is a procedure that was known in '78." In similar fashion, the district court held that the claimed subject matter would have been obvious in part because the "existence of monoclonal antibodies *having the affinity constants claimed in the patent was well known* prior to the alleged invention. . . ." [Emphasis ours.] Furthermore, there was not a shred of evidence that undue experimentation was required by those skilled in the art to practice the invention. We hold as a matter of law that the '110 patent disclosure is enabling.

2. *Best Mode*

HN12 "The specification . . . shall set forth the best mode contemplated by the inventor of carrying out his invention." 35 USC § 112. Because not complying with the best mode requirement amounts [**57] to concealing the preferred mode contemplated by the applicant at the time of filing, in order to find that the best mode requirement is not satisfied, it must be shown that [*1385] the applicant knew of and concealed a better mode than he disclosed. DeGeorge v. Bernier, 768 F.2d 1318, 1324, 226 U.S.P.Q. (BNA) 758, 763 (Fed. Cir. 1985) (quoting with approval *In re Sherwood*, 613 F.2d 809, 204 U.S.P.Q. (BNA) 537 (CCPA 1980)). The only evidence even colorably relating to concealment is testimony by various Hybritech employees that sophisticated, competent people perform the screening and that the screening process is labor-intensive and time-consuming. It is not plausible that this evidence amounts to proof of concealment of a best mode for screening or producing monoclonal antibodies for use in the claimed '110 process, and therefore we are of the firm conviction that the district court's finding that the best mode requirement was not satisfied is clearly erroneous.

3. *Indefiniteness*

The basis of the district court's holding that the claims are indefinite is that "they do not disclose how infringement may be avoided because antibody [**58] affinity cannot be estimated with any consistency." (Conclusion 6.) Even if the district court's finding in support of this holding -- that "there is no standard set of experimental conditions which are used to estimate affinities" -- is accurate, HN13 under the law pertaining to indefiniteness -- "if the claims, read in light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more," Shatterproof Glass Corp. v. Libbey-Owens Ford Co., 758 F.2d 613, 624, 225 U.S.P.Q. (BNA) 634, 641 (Fed. Cir. 1985) -- the claims clearly are definite. The evidence of record indisputably shows that calculating affinity was known in the art at the time of filing, and notwithstanding the fact that those calculations are not precise, or "standard," the claims, read in light of the specification, reasonably apprise those skilled in the art and are as precise as the subject matter permits. As a matter of law, no

court can demand more.

VI. [**59] *Motions*

Monoclonal's motion to strike Appendices A and B of Hybritech's reply brief as being beyond the page limit applicable to reply briefs is granted as to Appendix A but denied as to Appendix B, the latter having been helpful in culling the often non-supportive citations to the record by Monoclonal.

Hybritech's motion to supplement the record with a Monoclonal advertisement not considered at trial is denied. Any adverse impact that the disposition of these two motions has upon either party is more than outweighed by this court's patience with the seemingly endless flow of post-argument argumentative papers.

VII. *Conclusion*

The judgment of the district court holding the patent in suit invalid is *reversed* in all respects, and the case is *remanded* for a determination of the issue of infringement which the court held was moot.

REVERSED AND REMANDED.